

US3032171 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

Generated By: KC Joubran

Generated On: 11 Aug 2021 21:58:57

All time stamps listed in this document are displayed in GMT

US3032171

Form: Participant Creation

Data signed: (b) (4) 28 Sep 2020 17:21:16

Generated On: 11 Aug 2021 21:58:57

[Participant ID](#)

US3032171

[mRNA-1273-P301 Completion Guidelines](#)

US3032171

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 10 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SCRN |

US3032171

Folder: Screening

Form: Demographics

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Date of Birth (MMM yyyy) | (b) (6) 968 |
| Age | 52 |
| Age Units | YEARS |
| Age (Derived) | 52 |
| Sex | Female <input checked="" type="radio"/> Male <input type="radio"/> |
| Ethnicity | Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/> |
| Race (Check All That Apply) | |
| White | True |
| Black | False |
| Asian | False |
| American Indian or Alaska Native | False |
| Native Hawaiian or other Pacific Islander | False |
| Other | False |
| If race is Other, specify _____ | |
| Unknown | False |
| Not reported | False |

US3032171

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Date of Informed Consent (<i>dd MMM yyyy</i>) | 10 AUG 2020 |
| Month and Year of Informed Consent (derived) | AUG 2020 |
| Year of Informed Consent (derived) | 2020 |
| Protocol Version | Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/> |
| Was participant enrolled in the study? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, indicate reason for screen fail | Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/> |
| If reason for screen fail is Other, specify | |
| Was this participant screened previously? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If Yes, previous participant number | |
| Enrollment Trigger | 1 |

US3032171

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3032171

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

Were any significant conditions reported?

Yes ☒

No ☐

US3032171

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 01 Oct 2020 21:54:42

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Condition | POSTMENOPAUSAL |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3032171

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 01 Oct 2020 21:54:42

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Condition | EXERCISE-INDUCED ASTHMA |
| Start date (dd MMM yyyy) | UN UNK 2010 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2010 |
| Start Year (derived) | 2010 |
| Stop Month and Year (derived) | |
| Stop Year (derived) | |

US3032171

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 01 Oct 2020 21:54:42

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Condition | ESTROGEN DEFICIENCY |
| Start date (dd MMM yyyy) | UN UNK 2018 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 2018 |
| Start Year (derived) | 2018 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3032171

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 01 Oct 2020 21:54:42

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Condition | PENICILLIN ALLERGY-ANAPHYLAXIS |
| Start date (dd MMM yyyy) | UN UNK 1978 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1978 |
| Start Year (derived) | 1978 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3032171

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 01 Oct 2020 21:54:42

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Condition | AZITHROMYCIN ALLERGY |
| Start date (dd MMM yyyy) | UN UNK 1989 |
| Start date completely unknown | False |
| Condition ongoing at study entry | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If No, please specify the stop date (dd MMM yyyy) _____ | |
| Stop date completely unknown | False |
| Start Month and Year (derived) | JAN 1989 |
| Start Year (derived) | 1989 |
| Stop Month and Year (derived) | _____ |
| Stop Year (derived) | _____ |

US3032171

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 08 Oct 2020 15:30:25

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 10 AUG 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 12:58 (24 HR) |
| Vital Signs Date and Time (derived) | 10 AUG 2020 12:58 |
| Height (<i>xxx.x</i>) | 171.4 cm |
| Weight (<i>xxx.x</i>) | 64.9 kg |
| BMI (<i>xxx.x</i>) | 22.09139 kg/m ² |
| BMI units | KG/M2 |
| Temperature (<i>xxx.x</i>) | ND - Not Done |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | ND - Not Done |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | ND - Not Done |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | ND - Not Done |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3032171

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*) 10 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2018

Date of last menstruation unknown False

US3032171

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☒ No ☐

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3032171

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

| | |
|--|-------|
| Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) | False |
| Resides in high density housing (e.g., high rise apartments with shared entrances or elevators) | False |
| Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes) | False |
| Resides in a single family home (i.e., detached housing) | True |
| Other | False |
| Specify | |

US3032171

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 10 AUG 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT1 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 02 Nov 2020 22:05:23

Generated On: 11 Aug 2021 21:58:57

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 102684

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☒
 >=18 and <65 years and at risk ☐
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Oct 2020 15:30:35

Generated On: 11 Aug 2021 21:58:57

| | |
|--------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Oct 2020 15:30:35

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 10 AUG 2020 |
| Time of assessment (00:00-23:59) | 12:58 (24 HR) |
| Vital Signs Date and Time (derived) | 10 AUG 2020 12:58 |
| Temperature (xxx.x) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 63 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 110 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 76 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Oct 2020 15:30:35

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 10 AUG 2020 |
| Time of assessment (00:00-23:59) | 14:43 (24 HR) |
| Vital Signs Date and Time (derived) | 10 AUG 2020 14:43 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 60 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 116 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3032171

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 21:36:49

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 10 AUG 2020

What was the treatment time? (00:00-23:59) 14:10 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 14:10

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3032171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

13:30 (24 HR)

Collection date and time (derived)

10 AUG 2020 13:30

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 10 AUG 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 13:17 | 10 AUG 2020 13:17 |
| Nasopharyngeal Swab 2 | No | | |

US3032171

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:21:51

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

10 AUG 2020 14:47

PC Open Date & Time

10 AUG 2020 14:30

PC Close Date & Time

10 AUG 2020 17:00

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

Was any **MEDICATION TAKEN** today for pain or fever? Yes ☐ No ☒

Please confirm reason for pain or fever medication (may select more than one):

| | |
|----------------------|-------------------|
| PC Time Stamp | 10 AUG 2020 17:57 |
| PC Open Date & Time | 10 AUG 2020 17:55 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 2

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

11 AUG 2020 12:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 3

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

12 AUG 2020 12:36

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 4

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

13 AUG 2020 12:14

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 5

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

14 AUG 2020 12:02

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 6

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

15 AUG 2020 12:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 7

Thank you for agreeing to participate in this study. To evaluate the safety of the study vaccine you received, it is important to record all reactions that occur for the 7 days following the vaccination, including the day of vaccination.

After you leave the clinic, please try to complete the eDiary every evening for the 7 days. If you miss a day, you will have up until noon the next day to enter your symptoms from the previous day. If any symptoms are continuing on Day 7, or if you did not complete assessments on Day 7, you will receive alerts from the Diary app each day to confirm and enter any symptoms that continue beyond Day 7.

Please contact the study doctor if you have any concerning changes to your health. Concerning changes would include an issue that requires a visit to a healthcare provider such as a doctor, hospital, emergency room or urgent care; any underarm swelling/tenderness within the 7 days from receiving the vaccination or any symptom you perceive as severe.

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.

If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

If you take any medication for pain or fever, you will be asked whether it was to TREAT pain or fever that has already occurred, or to PREVENT pain or fever from occurring. Please report any medications taken to the study staff at your next phone call or clinic visit, whichever is sooner.

You will also be asked to measure injection site redness and swelling/hardness using the ruler provided.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

Was any **MEDICATION TAKEN** today for pain or fever?

Yes ☐

No ☒

Please confirm reason for pain or fever medication (may select more than one):

PC Time Stamp

16 AUG 2020 12:16

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☐

Does not interfere with activity ☒

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 14:48

PC Open Date & Time

10 AUG 2020 14:30

PC Close Date & Time

10 AUG 2020 17:00

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

Please select one response below

None ☒

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 17:56

PC Open Date & Time

10 AUG 2020 17:55

PC Close Date & Time

11 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 2

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 12:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 3

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:36

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 4

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:14

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 5

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:02

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 6

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 12:01

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 7

Please record - **PAIN AT INJECTION SITE.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

Is there any **REDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Yes ☐

No ☒

Please record - **UNDERARM GLAND SWELLING OR
TENDERNESS.**

None ☒

Please select one response below

Does not interfere with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or
interferes with some activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:16

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 1, 30 MINUTES AFTER
VACCINATION (AT STUDY
CLINIC)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 10 AUG 2020 14:48 |
| PC Open Date & Time | 10 AUG 2020 14:30 |
| PC Close Date & Time | 10 AUG 2020 17:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

Yes ☐

| | |
|----------------------|-------------------|
| PC Time stamp | 10 AUG 2020 17:56 |
| PC Open Date & Time | 10 AUG 2020 17:55 |
| PC Close Date & Time | 11 AUG 2020 11:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 11 AUG 2020 12:01 |
| PC Open Date & Time | 11 AUG 2020 12:00 |
| PC Close Date & Time | 12 AUG 2020 11:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 12 AUG 2020 12:35 |
| PC Open Date & Time | 12 AUG 2020 12:00 |
| PC Close Date & Time | 13 AUG 2020 11:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 13 AUG 2020 12:15 |
| PC Open Date & Time | 13 AUG 2020 12:00 |
| PC Close Date & Time | 14 AUG 2020 11:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

PRODUCTION RELEASE (v12.003

53 of 2616

EAB) (1725)

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 14 AUG 2020 12:03 |
| PC Open Date & Time | 14 AUG 2020 12:00 |
| PC Close Date & Time | 15 AUG 2020 11:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 15 AUG 2020 12:01 |
| PC Open Date & Time | 15 AUG 2020 12:00 |
| PC Close Date & Time | 16 AUG 2020 11:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some
interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

No interference with activity or
1-2 episodes/24 hours ☐

Some interference with activity
or >2 episodes/24 hours ☐

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

Did you receive any **MEDICAL ATTENTION** (doctor visit,
other) for any illness or symptoms?

No ☒

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

| | |
|------------------------------|-------------------|
| Yes <input type="checkbox"/> | |
| PC Time stamp | 16 AUG 2020 12:16 |
| PC Open Date & Time | 16 AUG 2020 12:00 |
| PC Close Date & Time | 17 AUG 2020 11:59 |

US3032171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:21:19

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:21:19

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:21:19

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:21:19

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 28 Sep 2020 17:21:19

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:21:19

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 21 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT2 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|---|
| Timepoint | Pre-Dose <input checked="" type="radio"/> |
| | Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 21 SEP 2020 |
| Time of assessment (00:00-23:59) | 12:25 (24 HR) |
| Vital Signs Date and Time (derived) | 21 SEP 2020 12:25 |
| Temperature (xxx.x) | 37.0 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 79 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 107 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|--|
| Timepoint | Pre-Dose <input type="radio"/> |
| | Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input type="radio"/> |
| | No <input checked="" type="radio"/> |
| Date of assessment (dd MMM yyyy) | |
| Time of assessment (00:00-23:59) | |
| Vital Signs Date and Time (derived) | |
| Temperature (xxx.x) | |
| Route of measurement | Oral <input type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | |
| Pulse units | |
| Respiratory Rate (xxx) | |
| Respiratory Rate units | |
| Systolic Blood Pressure (xxx) | |
| Systolic Blood Pressure units | |
| Diastolic Blood Pressure (xxx) | |
| Diastolic Blood Pressure units | |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☒
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment?

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3032171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

| | |
|---------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

| | |
|-------------------------------|-------------|
| Collection date (dd MMM yyyy) | 21 SEP 2020 |
|-------------------------------|-------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 13:03 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|-------------------|
| Collection date and time (derived) | 21 SEP 2020 13:03 |
|------------------------------------|-------------------|

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

| | | | |
|-------------------------------|---------------------------|---------------------------------|------------------------------------|
| Collection date (dd MMM yyyy) | | | 21 SEP 2020 |
| Lab Test | Was the sample collected? | Collection time (00:00 - 23:59) | Collection date and time (derived) |
| Nasopharyngeal Swab 1 | Yes | 12:37 | 21 SEP 2020 12:37 |
| Nasopharyngeal Swab 2 | No | | |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 28 Sep 2020 17:21:52

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 19 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT3 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 19 OCT 2020 |
| Time of assessment (00:00-23:59) | 10:10 (24 HR) |
| Vital Signs Date and Time (derived) | 19 OCT 2020 10:10 |
| Temperature (xxx.x) | 37.0 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 74 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 96 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 56 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 OCT 2020

Collection time (00:00-23:59)

10:18 (24 HR)

Collection date and time (derived)

19 OCT 2020 10:18

US3032171

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Oct 2020 14:49:33

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| TIMEPOINT | DAY 64 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 12 OCT 2020 12:00:41 |
| Patient Cloud Open Date & Time | 10 OCT 2020 00:01 |
| Patient Cloud Close Date & Time | 14 OCT 2020 23:59 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 71

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

17 OCT 2020 06:46:29

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 78

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 OCT 2020 06:59:44

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 92 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 07 NOV 2020 06:36:21 |
| Patient Cloud Open Date & Time | 07 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 11 NOV 2020 23:59 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 99 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 14 NOV 2020 06:11:05 |
| Patient Cloud Open Date & Time | 14 NOV 2020 00:01 |
| Patient Cloud Close Date & Time | 18 NOV 2020 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 103

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

21 NOV 2020 14:44:35

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 110

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

25 NOV 2020 05:39:34

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 117

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

02 DEC 2020 05:30:42

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 124 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 09 DEC 2020 05:43:56 |
| Patient Cloud Open Date & Time | 09 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 13 DEC 2020 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 131

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 DEC 2020 05:36:54

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 138

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

23 DEC 2020 05:25:05

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| TIMEPOINT | DAY 145 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 30 DEC 2020 06:36:12 |
| Patient Cloud Open Date & Time | 30 DEC 2020 00:01 |
| Patient Cloud Close Date & Time | 03 JAN 2021 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 152

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

06 JAN 2021 05:46:05

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 159 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 13 JAN 2021 05:37:33 |
| Patient Cloud Open Date & Time | 13 JAN 2021 00:01 |
| Patient Cloud Close Date & Time | 17 JAN 2021 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 166

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

20 JAN 2021 05:45:44

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 173

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

27 JAN 2021 05:33:40

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 180

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

03 FEB 2021 05:39:49

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| TIMEPOINT | DAY 187 |
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 10 FEB 2021 05:53:01 |
| Patient Cloud Open Date & Time | 10 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 14 FEB 2021 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 194 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Date and time of submission | 17 FEB 2021 05:30:56 |
| Patient Cloud Open Date & Time | 17 FEB 2021 00:01 |
| Patient Cloud Close Date & Time | 21 FEB 2021 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 201

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 FEB 2021 11:29:04

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 208

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

05 MAR 2021 12:37:23

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 215

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

12 MAR 2021 11:31:27

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 222

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

19 MAR 2021 12:00:26

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 229

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

24 MAR 2021 05:41:45

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 236 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 31 MAR 2021 05:45:12 |
| Patient Cloud Open Date & Time | 31 MAR 2021 00:01 |
| Patient Cloud Close Date & Time | 04 APR 2021 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 243

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

07 APR 2021 05:40:56

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 250

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

16 APR 2021 12:00:40

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 257 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input checked="" type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input checked="" type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/> |
| Date and time of submission | 21 APR 2021 05:42:48 |
| Patient Cloud Open Date & Time | 21 APR 2021 00:01 |
| Patient Cloud Close Date & Time | 25 APR 2021 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 264

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

No ☒

Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Date and time of submission

28 APR 2021 05:30:48

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 271 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 278 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 285 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 292

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 299 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 306

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 313 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 320 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 327

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 334 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 341 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 348 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 355

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 362

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 369

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 376 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 383

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 390

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 397

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 404

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 15 SEP 2021 00:01 |
| Patient Cloud Close Date & Time | 19 SEP 2021 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 411 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 418 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 425

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 432 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 439 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 446 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 453

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 460 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 467

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 474

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 481 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 488 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 495

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 502

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 22 DEC 2021 00:01 |
| Patient Cloud Close Date & Time | 26 DEC 2021 23:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 509

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 516 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 523

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 530 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 537

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 544 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 551

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 558

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 565 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 572

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 579

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 586

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 593

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

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27 MAR 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 600 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

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03 APR 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 607

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

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10 APR 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 614 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 621 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 628 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 635 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 642

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

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| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

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15 MAY 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 649 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 656 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 663

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

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05 JUN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 670 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

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12 JUN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 677

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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15 JUN 2022 00:01

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19 JUN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 684

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

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26 JUN 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 691 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

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29 JUN 2022 00:01

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03 JUL 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 698

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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10 JUL 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 705 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

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13 JUL 2022 00:01

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17 JUL 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 712 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

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24 JUL 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 719 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

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31 JUL 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 726 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 733

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature \geq 100.4°F/38°C) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 740 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 747 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 754

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 761 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature \geq 100.4°F/38°C) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 768 |
|---|---|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="radio"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="radio"/> Yes <input type="radio"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 775

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 782

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

I confirm I have read this message and will call the study clinic immediately ☐

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) ☐
Chills ☐
Cough ☐
Shortness of breath ☐
Difficulty breathing ☐
Fatigue ☐
Muscle aches ☐
Body aches ☐
Headache ☐
New loss of taste ☐
New loss of smell ☐
Sore throat ☐
Congestion ☐
Runny nose ☐
Nausea ☐
Vomiting ☐
Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐
Yes ☐

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| TIMEPOINT | DAY 796 |
|---|--|
| Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |
| Please identify below which symptoms you have experienced or are experiencing (Check all that apply): | |
| Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$) | <input type="checkbox"/> |
| Chills | <input type="checkbox"/> |
| Cough | <input type="checkbox"/> |
| Shortness of breath | <input type="checkbox"/> |
| Difficulty breathing | <input type="checkbox"/> |
| Fatigue | <input type="checkbox"/> |
| Muscle aches | <input type="checkbox"/> |
| Body aches | <input type="checkbox"/> |
| Headache | <input type="checkbox"/> |
| New loss of taste | <input type="checkbox"/> |
| New loss of smell | <input type="checkbox"/> |
| Sore throat | <input type="checkbox"/> |
| Congestion | <input type="checkbox"/> |
| Runny nose | <input type="checkbox"/> |
| Nausea | <input type="checkbox"/> |
| Vomiting | <input type="checkbox"/> |
| Diarrhea | <input type="checkbox"/> |
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
| Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? | No <input type="checkbox"/> Yes <input type="checkbox"/> |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. | I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/> |
|---|--|

| | |
|---|-------------------|
| Date and time of submission | |
| Patient Cloud Open Date & Time | 12 OCT 2022 00:01 |
| Patient Cloud Close Date & Time | 16 OCT 2022 23:59 |

US3032171

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 21:58:57

| Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other? | Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache? | Date & Time of Submission |
|---|--|---------------------------|
| No | | 05 MAR 2021 12:37:09 |

US3032171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Dec 2020 19:47:51

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Dec 2020 19:47:51

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Dec 2020 15:53:54

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Dec 2020 15:53:54

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:22:00

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:35:51

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 19 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | VISIT4 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:58:57

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3032171

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:58:57

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3032171

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 18:22:00

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 18:22:00

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted? Yes ☐
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Data signed: (b) (4) 28 Sep 2020 17:21:17

Generated On: 11 Aug 2021 21:58:57

| | |
|--|--|
| Date of Contact | 08 SEP 2020 |
| Time of Contact | 10:00 |
| Date and Time of Contact (derived) | 08 SEP 2020 10:00 |
| Type of Contact | <div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div> |
| Has the subject reported symptoms of SARS-COV-2? | <div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|----------------------------------|
| Day 1 | <input checked="" type="radio"/> |
| Day 2 | <input type="radio"/> |
| Day 3 | <input type="radio"/> |
| Day 4 | <input type="radio"/> |
| Day 5 | <input type="radio"/> |
| Day 6 | <input type="radio"/> |
| Day 7 | <input type="radio"/> |
| Day 8 | <input type="radio"/> |
| Day 9 | <input type="radio"/> |
| Day 10 | <input type="radio"/> |
| Day 11 | <input type="radio"/> |
| Day 12 | <input type="radio"/> |
| Day 13 | <input type="radio"/> |
| Day 14 | <input type="radio"/> |
| Day 15 | <input type="radio"/> |
| Day 16 | <input type="radio"/> |
| Day 17 | <input type="radio"/> |
| Day 18 | <input type="radio"/> |
| Day 19 | <input type="radio"/> |
| Day 20 | <input type="radio"/> |
| Day 21 | <input type="radio"/> |
| Day 22 | <input type="radio"/> |
| Day 23 | <input type="radio"/> |
| Day 24 | <input type="radio"/> |
| Day 25 | <input type="radio"/> |
| Day 26 | <input type="radio"/> |
| Day 27 | <input type="radio"/> |
| Day 28 | <input type="radio"/> |
| Day 29 | <input type="radio"/> |
| Day 30 | <input type="radio"/> |
| Day 31 | <input type="radio"/> |
| Day 32 | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|---------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 05 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

285 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input checked="" type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 06 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

289 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input checked="" type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|---------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 07 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | ND - Not Done | |
| O2 Saturation Units | % | |
| Temperature | ND - Not Done | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

293 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

294 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input checked="" type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|-------------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 08 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 100 % | |
| O2 Saturation Units | % | |
| Temperature | 37.0 C | |
| Chills | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Cough | None | <input type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input checked="" type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Shortness of Breath | None | <input type="checkbox"/> |
| | Mild | <input checked="" type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |
| | Not Done | <input type="checkbox"/> |
| Difficulty Breathing | None | <input checked="" type="checkbox"/> |
| | Mild | <input type="checkbox"/> |
| | Moderate | <input type="checkbox"/> |
| | Severe | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input checked="" type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 09 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

301 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

302 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input checked="" type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|-----------------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 10 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 100 % | |
| O2 Saturation Units | % | |
| Temperature | 98.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| PRODUCTION RELEASE (v12.003 | 305 of 2616 | |
| EAB) (1725) | | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

306 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input checked="" type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 11 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 100 % | |
| O2 Saturation Units | % | |
| Temperature | 98.3 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

309 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

310 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input checked="" type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 12 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

313 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input checked="" type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 13 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.5 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input checked="" type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

317 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|-------------------------|----------|----------------------------------|
| Nasal Congestion | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Runny Nose (Rhinorrhea) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Nausea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Vomiting | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Diarrhea | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Sore Throat | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input checked="" type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 14 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.7 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

321 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input checked="" type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 15 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.2 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

325 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

326 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input checked="" type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 16 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 97.6 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

329 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input checked="" type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 17 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.2 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

333 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input checked="" type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 18 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.4 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

337 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input checked="" type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 19 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

341 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input checked="" type="checkbox"/> |
| Day 17 | <input type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 20 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.0 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

345 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

346 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Symptom Day

| | |
|--------|-------------------------------------|
| Day 1 | <input type="checkbox"/> |
| Day 2 | <input type="checkbox"/> |
| Day 3 | <input type="checkbox"/> |
| Day 4 | <input type="checkbox"/> |
| Day 5 | <input type="checkbox"/> |
| Day 6 | <input type="checkbox"/> |
| Day 7 | <input type="checkbox"/> |
| Day 8 | <input type="checkbox"/> |
| Day 9 | <input type="checkbox"/> |
| Day 10 | <input type="checkbox"/> |
| Day 11 | <input type="checkbox"/> |
| Day 12 | <input type="checkbox"/> |
| Day 13 | <input type="checkbox"/> |
| Day 14 | <input type="checkbox"/> |
| Day 15 | <input type="checkbox"/> |
| Day 16 | <input type="checkbox"/> |
| Day 17 | <input checked="" type="checkbox"/> |
| Day 18 | <input type="checkbox"/> |
| Day 19 | <input type="checkbox"/> |
| Day 20 | <input type="checkbox"/> |
| Day 21 | <input type="checkbox"/> |
| Day 22 | <input type="checkbox"/> |
| Day 23 | <input type="checkbox"/> |
| Day 24 | <input type="checkbox"/> |
| Day 25 | <input type="checkbox"/> |
| Day 26 | <input type="checkbox"/> |
| Day 27 | <input type="checkbox"/> |
| Day 28 | <input type="checkbox"/> |
| Day 29 | <input type="checkbox"/> |
| Day 30 | <input type="checkbox"/> |
| Day 31 | <input type="checkbox"/> |
| Day 32 | <input type="checkbox"/> |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|----------------------|-------------|----------------------------------|
| | Day 33 | <input type="checkbox"/> |
| | Day 34 | <input type="checkbox"/> |
| | Day 35 | <input type="checkbox"/> |
| | Day 36 | <input type="checkbox"/> |
| | Day 37 | <input type="checkbox"/> |
| | Day 38 | <input type="checkbox"/> |
| | Day 39 | <input type="checkbox"/> |
| | Day 40 | <input type="checkbox"/> |
| Date | 21 SEP 2020 | |
| Assessment Not Done | False | |
| O2 Saturation | 99 % | |
| O2 Saturation Units | % | |
| Temperature | 98.1 F | |
| Chills | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Cough | None | <input type="radio"/> |
| | Mild | <input checked="" type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Shortness of Breath | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Difficulty Breathing | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

349 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|------------------------|----------|----------------------------------|
| | Not Done | <input type="radio"/> |
| Fatigue | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Muscle Aches (Myalgia) | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Body Aches | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| Headache | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Taste | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |
| New Loss of Smell | None | <input checked="" type="radio"/> |
| | Mild | <input type="radio"/> |
| | Moderate | <input type="radio"/> |
| | Severe | <input type="radio"/> |
| | Not Done | <input type="radio"/> |

PRODUCTION RELEASE (v12.003

EAB) (1725)

350 of 2616

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 24 Nov 2020 20:28:34

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| Date of Visit | 08 SEP 2020 |
| Was the Subject Tested For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Did Subject Test Positive For SARS-CoV-2 by RT-PCR? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of Test | 08 SEP 2020 |
| Type of Test Performed | Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/> |
| Other, specify | |
| Was this diagnostic test performed at a lab other than the Study Central Lab? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If yes, provide lab information below | |
| Lab/ Institution Test Performed | |
| CLIA Certified? | Yes <input type="radio"/> No <input type="radio"/> |
| COVID-19 Positive (CSA Programming Field Only) | 1 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Nov 2020 20:28:34

Generated On: 11 Aug 2021 21:58:57

Did the subject have Respiratory Rates ≥ 30 per Minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Respiratory Rate _____

Did the subject have Heart Rate ≥ 125 beats per minute? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Heart Rate _____

Did the subject have Oxygen Saturation of SpO₂ $\leq 93\%$ on room air at sea level? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

Oxygen Saturation _____

Did the subject have PaO₂/FIO₂ Ratio < 300 mm Hg? Yes ☐ No ☒

If Yes, provide:

Start Date _____

End Date _____

PaO₂ _____

Did the subject have Respiratory failure? Yes ☐ No ☒

Start Date _____

Did the subject have Acute Respiratory Distress Syndrome (ARDS)? Yes ☐ No ☒

Start Date _____

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Nov 2020 20:28:34

Generated On: 11 Aug 2021 21:58:57

If Yes to either Did subject require any of the following:

Ventilator Support:

High-Flow Oxygen? Yes ☐ No ☒

Start Date

End Date

Non-Invasive Ventilation? Yes ☐ No ☒

Start Date

End Date

Mechanical Ventilation? Yes ☐ No ☒

Start Date

End Date

ECMO? Yes ☐ No ☒

Start Date

End Date

Evidence of Shock:

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg Yes ☐ No ☒

Start Date

End Date

Evidence of Shock Requires Vasopressors Yes ☐ No ☒

Start Date

End Date

Acute Renal Dysfunction? Yes ☐ No ☒

Start Date

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Data signed: (b) (4) 24 Nov 2020 20:28:34

Generated On: 11 Aug 2021 21:58:57

Hepatic Dysfunction? Yes ☐
No ☒

Start Date

Neurologic Dysfunction? Yes ☐
No ☒

Start Date

Evidence of Pneumonia:

Clinical Evidence Yes ☐
No ☒

Date of Assessment

Radiographical Evidence Yes ☐
No ☒

Date of Assessment

Admission to an intensive care unit due to SARS-CoV-2 Yes ☐
No ☒

Start Date

End Date

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 08 Dec 2020 19:47:17

Generated On: 11 Aug 2021 21:58:57

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 16 Dec 2020 20:09:11

Generated On: 11 Aug 2021 21:58:57

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 10 SEP 2020 |
| Day 5 | Yes | 12 SEP 2020 |
| Day 7 | Yes | 14 SEP 2020 |
| Day 9 | Yes | 16 SEP 2020 |
| Day 14 | Yes | 21 SEP 2020 |
| Day 21 | Yes | 28 SEP 2020 |
| Day 28 | Yes | 6 OCT 2020 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection

Data signed: (b) (4) 09 Apr 2021 18:06:45

Generated On: 11 Aug 2021 21:58:57

| Visit | Was Saliva Collected? | Date of Collection |
|--------|-----------------------|--------------------|
| Day 3 | Yes | 10 SEP 2020 |
| Day 5 | Yes | 12 SEP 2020 |
| Day 7 | Yes | 14 SEP 2020 |
| Day 9 | Yes | 16 SEP 2020 |
| Day 14 | Yes | 21 SEP 2020 |
| Day 21 | Yes | 28 SEP 2020 |
| Day 28 | Yes | 5 OCT 2020 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 21:36:49

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 8 SEP 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD1 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:36:08

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 8 SEP 2020 |
| Time of assessment (00:00-23:59) | 11:05 (24 HR) |
| Vital Signs Date and Time (derived) | 8 SEP 2020 11:05 |
| Temperature (xxx.x) | 37.0 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 128 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 63 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 21:36:49

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 10 Nov 2020 21:36:49

Generated On: 11 Aug 2021 21:58:57

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

8 SEP 2020

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 08 Oct 2020 15:30:24

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 6 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD28 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 14:18:14

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 6 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 08:03 (24 HR) |
| Vital Signs Date and Time (derived) | 6 OCT 2020 08:03 |
| Temperature (<i>xxx.x</i>) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 103 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 69 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Oct 2020 15:30:24

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 08 Oct 2020 15:30:24

Generated On: 11 Aug 2021 21:58:57

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

6 OCT 2020

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 10 Nov 2020 21:36:49

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 6 OCT 2020 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | SICKD28 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Mar 2021 14:18:14

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 6 OCT 2020 |
| Time of assessment (<i>00:00-23:59</i>) | 08:03 (24 HR) |
| Vital Signs Date and Time (derived) | 6 OCT 2020 08:03 |
| Temperature (<i>xxx.x</i>) | 36.8 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 73 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 14 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 103 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 69 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 10 Nov 2020 21:36:49

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 10 Nov 2020 21:36:49

Generated On: 11 Aug 2021 21:58:57

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

6 OCT 2020

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 9 JAN 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | UNBLND_DECIDE |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 18 Mar 2021 21:13:54

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Date of updated informed consent (<i>dd MMM yyyy</i>) | 9 JAN 2021 |
| N/A - Subject Unblinded under Amendment 5 and Discontinued from Study | False |
| Was the participant unblinded? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Under what version of the Protocol was the Participant unblinded? | Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/> |
| Date of unblinding (<i>dd MMM yyyy</i>) | 9 JAN 2021 |
| Participant randomization assignment | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> |
| Actual Dose 1 | mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/> |
| Actual Dose 2 | mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/> |
| Will participant receive mRNA-1273? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Placebo Only Flag | 1 |
| Continuing with mRNA-1273 | 1 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 9 JAN 2021 |
| Time of assessment (00:00-23:59) | 11:27 (24 HR) |
| Vital Signs Date and Time (derived) | 9 JAN 2021 11:27 |
| Temperature (xxx.x) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 67 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 101 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 78 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| BMI (xxx.x) | |
| Timepoint | Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 9 JAN 2021 |
| Time of assessment (00:00-23:59) | 13:15 (24 HR) |
| Vital Signs Date and Time (derived) | 9 JAN 2021 13:15 |
| Temperature (xxx.x) | 36.7 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 103 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 85 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 JAN 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 9 JAN 2021

What was the treatment time? (00:00-23:59) 12:45 (24 HR)

Treatment Date and Time (derived) 9 JAN 2021 12:45

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

| | |
|---------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

| | |
|-------------------------------|------------|
| Collection date (dd MMM yyyy) | 9 JAN 2021 |
|-------------------------------|------------|

| | |
|-------------------------------|---------------|
| Collection time (00:00-23:59) | 10:59 (24 HR) |
|-------------------------------|---------------|

| | |
|------------------------------------|------------------|
| Collection date and time (derived) | 9 JAN 2021 10:59 |
|------------------------------------|------------------|

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

| | |
|---------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |

| | |
|-------------------------------|------------|
| Collection date (dd MMM yyyy) | 9 JAN 2021 |
|-------------------------------|------------|

| | |
|---------------------------------|-------|
| Collection time (00:00 - 23:59) | 11:11 |
|---------------------------------|-------|

| | |
|------------------------------------|------------------|
| Collection Date and Time (derived) | 9 JAN 2021 11:11 |
|------------------------------------|------------------|

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 18 Jan 2021 19:28:13

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

| | |
|--|--------------------------------------|
| Is the participant continuing to the next visit? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Continuing Flag | 1 |
| OLD29 Placebo Flag | 1 |

US3032171

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 9 FEB 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD29 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

| | |
|--------|---------------|
| Height | ND - Not Done |
| Weight | ND - Not Done |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|--|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/> |
| Were vital signs assessed? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Date of assessment (dd MMM yyyy) | 9 FEB 2021 |
| Time of assessment (00:00-23:59) | 11:01 (24 HR) |
| Vital Signs Date and Time (derived) | 9 FEB 2021 11:01 |
| Temperature (xxx.x) | 37.2 C |
| Route of measurement | Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/> |
| If Other, specify | |
| Pulse (xxx) | 70 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 111 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 74 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

| | |
|-------------------------------------|---|
| Height | ND - Not Done |
| Weight | ND - Not Done |
| Timepoint | Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/> |
| Were vital signs assessed? | Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> |
| Date of assessment (dd MMM yyyy) | 9 FEB 2021 |
| Time of assessment (00:00-23:59) | 12:22 (24 HR) |
| Vital Signs Date and Time (derived) | 9 FEB 2021 12:22 |
| Temperature (xxx.x) | 37.0 C |
| Route of measurement | Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/> |
| If Other, specify | |
| Pulse (xxx) | 64 beats/min |
| Pulse units | BPM |
| Respiratory Rate (xxx) | 16 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (xxx) | 124 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (xxx) | 84 mmHg |
| Diastolic Blood Pressure units | MMHG |

US3032171

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 9 FEB 2021

What was the treatment time? (00:00-23:59) 11:49 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 11:49

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3032171

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Feb 2021 19:55:22

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:58:57

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3032171

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 15:35:52

Generated On: 11 Aug 2021 21:58:57

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3032171

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 06 Apr 2021 15:36:08

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Was this visit performed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Visit date (dd MMM yyyy) | 19 MAR 2021 |
| Was visit performed at the participant's home or at the clinic? | Home <input type="radio"/> |
| | Clinic <input checked="" type="radio"/> |
| Folder OID | OLD57 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 06 Apr 2021 15:36:09

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---------------------------------------|
| Were vital signs assessed? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Date of assessment (<i>dd MMM yyyy</i>) | 19 MAR 2021 |
| Time of assessment (<i>00:00-23:59</i>) | 10:15 (24 HR) |
| Vital Signs Date and Time (derived) | 19 MAR 2021 10:15 |
| Temperature (<i>xxx.x</i>) | 36.9 C |
| Route of measurement | Oral <input checked="" type="radio"/> |
| | Axillary <input type="radio"/> |
| | Other <input type="radio"/> |
| If Other, specify | |
| Pulse (<i>xxx</i>) | 66 beats/min |
| Pulse units | BPM |
| Respiratory Rate (<i>xxx</i>) | 17 breaths/min |
| Respiratory Rate units | BREATHS/MIN |
| Systolic Blood Pressure (<i>xxx</i>) | 97 mmHg |
| Systolic Blood Pressure units | MMHG |
| Diastolic Blood Pressure (<i>xxx</i>) | 65 mmHg |
| Diastolic Blood Pressure units | MMHG |
| Height (derived) | |
| Weight (derived) | |

US3032171

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 06 Apr 2021 15:36:08

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3032171

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 06 Apr 2021 15:36:08

Generated On: 11 Aug 2021 21:58:57

| | |
|------------------------------------|--------------------------------------|
| Was the sample collected? | Yes <input checked="" type="radio"/> |
| | No <input type="radio"/> |
| Collection date (dd MMM yyyy) | 19 MAR 2021 |
| Collection time (00:00-23:59) | 10:25 (24 HR) |
| Collection date and time (derived) | 19 MAR 2021 10:25 |

US3032171

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Sep 2020 17:21:16

Generated On: 11 Aug 2021 21:58:57

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | |
|--|--|
| AEID | USA-US032-2020-MRNA-1273-P30 1000005 |
| Adverse event | COVID-19 |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Start date (dd MMM yyyy) | 05 SEP 2020 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | 24 SEP 2020 |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |

PRODUCTION RELEASE (v12.003
EAB) (1725)

397 of 2616

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | |
|--|---|
| Number of Days in ICU | |
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/> |
| Other action taken (check all that apply) | |
| None | True |
| Concomitant Medication | False |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: | |
| Narrative | SUBJECTS TEST WAS POSITIVE 08SEP2020 |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | |

PRODUCTION RELEASE (v12.003
EAB) (1725)

398 of 2616

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

AEID

Adverse event

GENERALIZED URTICARIA

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

24 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

399 of 2616

EAB) (1725)

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | _____ |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | |
|--|--|
| AEID | |
| Adverse event | RIGHT HIP PAIN |
| Was this a medically-attended AE? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| Was this a Solicited Adverse Reaction? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Is this event a confirmed diagnosis of Symptomatic Covid-19? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Start date (dd MMM yyyy) | 17 MAR 2021 |
| Start time (00:00-23:59) | |
| AE start date and time (derived) | |
| Ongoing? | Yes <input checked="" type="radio"/> No <input type="radio"/> |
| If not Ongoing, end date (dd MMM yyyy) | |
| End time (00:00-23:59) | |
| AE End Date and Time (derived) | |
| Severity | Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/> |
| Is the adverse event serious? | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| AE is serious due To (check all that apply) | |
| Death | False |
| Life threatening | False |
| Requires inpatient or prolongation of existing Hospitalization | False |
| Hospital Admission Date (dd MMM yyyy) | |
| Hospital Discharge Date (dd MMM yyyy) | |
| Admitted to ICU? | Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/> |
| Number of Days in ICU | |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | |
|---|---|
| Persistent or significant disability or incapacity | False |
| Congenital anomaly or birth defect | False |
| Other medically important event | False |
| Relationship to investigational product | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Relationship to Study Procedure | Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/> |
| Action taken with investigational product | None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/> |
| Other action taken (check all that apply) | |
| None | False |
| Concomitant Medication | True |
| Concomitant Procedure | False |
| Outcome | Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/> |
| If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ | |
| Narrative _____ | |
| Serious Adverse Event Derived (CSA Programming Field Only) | 0 |
| Medically Attended AE Derived (CSA Programming Field Only) | 1 |
| Admitted to ICU Derived (CSA Programming Field Only) | _____ |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 28 Sep 2020 17:21:16

Generated On: 11 Aug 2021 21:58:57

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication MONTELUKAST SODIUM

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
EXERCISE-INDUCED ASTHMA

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

404 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2010 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication FLOVENT HFA

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
EXERCISE-INDUCED ASTHMA

Dose per administration 110

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

406 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input checked="" type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | UN | UNK 2010 |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication ALBUTEROL INHALER

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY:
EXERCISE-INDUCED ASTHMA

Dose per administration 90

Dose unit mg ☐
ug ☒
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

408 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input checked="" type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN UNK 2010 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="checkbox"/> |
| | No | <input type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication PREMPRO

Prophylaxis Yes ☐
No ☒

Indication MEDICAL HISTORY: ESTROGEN
HORMONE DEFICIENCY

Dose per administration 0.125/5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

410 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|----------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | UN MAY 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT:
GENERALIZED URTICARIA

Dose per administration 40

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

412 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 14 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 17 SEP 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT:
GENERALIZED URTICARIA

Dose per administration 30

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

414 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 18 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 22 SEP 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT:
GENERALIZED URTICARIA

Dose per administration 20

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

416 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 23 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 28 SEP 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication ADVERSE EVENT:
GENERALIZED URTICARIA

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

418 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 29 SEP 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | 05 OCT 2020 | |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input checked="" type="checkbox"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication SEASONAL INFLUENZA
VACCINE

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS FOR SEASONAL
INFLUENZA

Dose per administration 0.5

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☒
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

420 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|-------------------------------------|
| | Intraocular | <input type="checkbox"/> |
| | Intramuscular | <input checked="" type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify | | |
| Start date (dd MMM yyyy) | 07 OCT 2020 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| If not Ongoing, End date (dd MMM yyyy) | | 07 OCT 2020 |
| Was this medication taken for solicited event? | Yes | <input type="checkbox"/> |
| | No | <input checked="" type="checkbox"/> |
| Separate Dosage Number (derived) | | |
| Interval Dosage Unit Number (derived) | | |
| Interval Dosage Definition (derived) | 802 | <input type="checkbox"/> |
| | 803 | <input type="checkbox"/> |
| | 804 | <input type="checkbox"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP PAIN

Dose per administration 800

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☒
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

422 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 17 MAR 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 3 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

Name of Medication CELEBREX

Prophylaxis Yes ☐
No ☒

Indication RIGHT HIP PAIN

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

424 of 2616

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 23 Apr 2021 19:37:07

Generated On: 11 Aug 2021 21:58:57

| | | |
|--|--------------------------|----------------------------------|
| | Intramuscular | <input type="checkbox"/> |
| | Respiratory (Inhalation) | <input type="checkbox"/> |
| | Intralesional | <input type="checkbox"/> |
| | Intraperitoneal | <input type="checkbox"/> |
| | Nasal | <input type="checkbox"/> |
| | Vaginal | <input type="checkbox"/> |
| | Rectal | <input type="checkbox"/> |
| | Intravenous | <input type="checkbox"/> |
| | Intravenous Bolus | <input type="checkbox"/> |
| | Intravenous Drip | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| If route of administration is Other, specify _____ | | |
| Start date (dd MMM yyyy) | 20 APR 2021 | |
| Start date completely unknown | False | |
| Ongoing? | Yes | <input checked="" type="radio"/> |
| | No | <input type="radio"/> |
| If not Ongoing, End date (dd MMM yyyy) _____ | | |
| Was this medication taken for solicited event? | Yes | <input type="radio"/> |
| | No | <input checked="" type="radio"/> |
| Separate Dosage Number (derived) | 1 | |
| Interval Dosage Unit Number (derived) | 1 | |
| Interval Dosage Definition (derived) | 802 | <input type="radio"/> |
| | 803 | <input type="radio"/> |
| | 804 | <input checked="" type="radio"/> |

US3032171

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 28 Sep 2020 17:21:16

Generated On: 11 Aug 2021 21:58:57

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3032171

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 10 Nov 2020 21:36:49

Generated On: 11 Aug 2021 21:58:57

Date of dosing discontinuation (dd MMM yyyy) 21 SEP 2020

Primary reason for dosing discontinuation

| | |
|--|-------------------------------------|
| AE (specify) | <input type="checkbox"/> |
| SAE (specify) | <input type="checkbox"/> |
| Death | <input type="checkbox"/> |
| Lost To Follow-up | <input type="checkbox"/> |
| Physician decision (specify) | <input type="checkbox"/> |
| Pregnancy | <input type="checkbox"/> |
| Protocol deviation (specify) | <input type="checkbox"/> |
| Study Terminated By Sponsor | <input type="checkbox"/> |
| Withdrawal of consent by participant (specify) | <input type="checkbox"/> |
| Due to SARS-COV-2 | <input checked="" type="checkbox"/> |
| Other | <input type="checkbox"/> |

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

US3032171

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 21:58:57

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 10 Dec 2020 16:21:22

Generated On: 11 Aug 2021 21:58:57

| | |
|--|--|
| SAEID | USA-US032-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | KEITH |
| Investigator's Last Name | VRBICKY |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 10 Dec 2020 16:21:22

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| SAEID | USA-US032-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | KEITH |
| Investigator's Last Name | VRBICKY |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 22/SEP/2020 09:51 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 10 Dec 2020 16:21:22

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| SAEID | USA-US032-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | KEITH |
| Investigator's Last Name | VRBICKY |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 05/OCT/2020 09:49 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 10 Dec 2020 16:21:22

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| SAEID | USA-US032-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | KEITH |
| Investigator's Last Name | VRBICKY |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 12/OCT/2020 12:52 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 10 Dec 2020 16:21:22

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| SAEID | USA-US032-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | KEITH |
| Investigator's Last Name | VRBICKY |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 19/NOV/2020 13:29 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 10 Dec 2020 16:21:22

Generated On: 11 Aug 2021 21:58:57

| | |
|---|--|
| SAEID | USA-US032-2020-MRNA-1273-P301000005 |
| Serious | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Death | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Life threatening | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Requires inpatient or prolongation of existing Hospitalization | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Persistent or significant disability or incapacity | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Congenital anomaly or birth defect | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Other medically important event | Yes <input type="radio"/> No <input checked="" type="radio"/> |
| Investigator's First Name | KEITH |
| Investigator's Last Name | VRBICKY |
| Site Address: Street | |
| Site Address: City | |
| Site Address: State | |
| Site Address: Postal Code | |
| Investigator Country | US |
| E2B Transmit Flag (Derived/Hidden) | 5 |
| Date of submission (Pre-filled from custom function) | 09/DEC/2020 11:09 |
| Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge. | True |

Audit

US3032171 (Prod: Meridian Clinical Research (Norfolk-Nebraska))

US3032171

Form: Participant Creation

Generated On: 11 Aug 2021 21:58:57

[Participant ID](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 14 Apr 2021 14:48:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'US3032171' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Aug 2020 18:09:19 |

US3032171

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:02 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:32 |

US3032171

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:02 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Aug 2020 18:09:20 |

US3032171

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:02 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Clinic (Clinic)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:32 |

US3032171

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'SCRN' | System | 11 Aug 2020 15:13:32 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

Date of Birth (MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered (b) (6) 1968' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Aug 2020 18:09:21 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Age](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '52' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Age Units](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'YEARS' | System | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Age \(Derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered '52' | System | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Sex](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Female (F)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Ethnicity](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[White](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'l' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Black](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Asian](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[American Indian or Alaska Native](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Native Hawaiian or other Pacific Islander](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Other](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[If race is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 21:58:57

[Not reported](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:14:41 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

Date of Informed Consent (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

[Month and Year of Informed Consent \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'Aug 2020' | System | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

[Year of Informed Consent \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered '2020' | System | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

[Protocol Version](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Amendment 2 (2)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

[Was participant enrolled in the study?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

[If No, indicate reason for screen fail](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

If reason for screen fail is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

[Was this participant screened previously?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

[If Yes, previous participant number](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Aug 2020 18:09:20 |

US3032171

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 21:58:57

[Enrollment Trigger](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'I' | System | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 21:58:57

[Did the participant meet all eligibility criteria?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:49:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:29 |

US3032171

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 21:58:57

[Were any significant conditions reported?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:02 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:17:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Condition](#)

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 11 Aug 2020 15:22:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 15:22:17 |
| Data point term sent to Coder | System | 11 Aug 2020 15:20:57 |
| User entered 'postmenopausal' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:20:02 |
| | (b) (4) | |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'un UNK 2018' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'Jan 2018' | System | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered '2018' | System | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 21:58:57

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:20:02 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Condition](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma exercise induced, LLT: Exercise induced asthma - version MedDRA\\23.0. | (b) (4) (b) (4) Coder Import (b) (4) | 11 Aug 2020 15:22:17 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 11 Aug 2020 15:22:17 |
| Data point term sent to Coder | System | 11 Aug 2020 15:20:59 |
| User entered 'exercise-induced asthma' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'un UNK 2010' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'Jan 2010' | System | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered '2010' | System | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 21:58:57

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:20:20 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

Condition

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User coded data point as SOC: Endocrine disorders, HLG: Endocrine disorders of gonadal function, HLT: Endocrine abnormalities of gonadal function NEC, PT: Oestrogen deficiency, LLT: Estrogen deficiency - version MedDRA\23.0. | (b) (4) (b) (4) Coder Import (b) (4) | 30 Sep 2020 14:03:57 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. | Coder Import (b) (4) | 30 Sep 2020 14:03:57 |
| Data point term sent to Coder | System | 29 Sep 2020 22:04:06 |
| User closed query 'For coding purposes, please specify the name/type of hormone deficiency and update the term accordingly' (Site from System). | System | 29 Sep 2020 22:03:22 |
| Query 'For coding purposes, please specify the name/type of hormone deficiency and update the term accordingly' answered with 'updated' (Site from System). | Samantha Wieseler (b) (4) | 29 Sep 2020 22:03:22 |
| User entered 'Estrogen DEFICIENCY' reason for change: Data Entry Error | Samantha Wieseler (b) (4) | 29 Sep 2020 22:03:17 |
| User opened query 'For coding purposes, please specify the name/type of hormone deficiency and update the term accordingly' (Site from System). | (b) (4) (b) (4) Coder Import (b) (4) | 14 Aug 2020 15:30:14 |
| Data point term sent to Coder | System | 11 Aug 2020 15:20:59 |
| User entered 'hormone deficiency' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:20:37 |
| | (b) (4) | |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'un UNK 2018' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'Jan 2018' | System | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered '2018' | System | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 21:58:57

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:20:37 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

Condition

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Anaphylactic and anaphylactoid responses, PT: Anaphylactic reaction, LLT: Anaphylactic reaction to drug - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Jan 2021 16:30:50 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 24 Jan 2021 16:30:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0. | Coder Import (b) (4) | 3 Aug 2020 12:33:20 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | 13 Aug 2020 12:33:20 |
| Data point term sent to Coder | System | 11 Aug 2020 15:22:02 |
| User entered 'penicillin allergy-anaphylaxis' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'un UNK 1978' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'Jan 1978' | System | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered '1978' | System | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 21:58:57

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:21:04 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

Condition

| Audit | User | Time (GMT) |
|--|---------------------------------|---------------------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | (b) (4) | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | (b) (4) 19 Sep 2020 18:27:52 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | (b) (4) 19 Sep 2020 18:27:52 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\\23.0. | Coder Import (b) (4) | (b) (4) 17 Sep 2020 15:46:38 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) | (b) (4) 17 Sep 2020 15:46:38 |
| User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0. | Coder Import (b) (4) | (b) (4) 11 Aug 2020 15:23:20 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | (b) (4) 11 Aug 2020 15:23:20 |
| Data point term sent to Coder | System | 11 Aug 2020 15:22:05 |
| User entered 'azithromycin allergy' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'un UNK 1989' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[Condition ongoing at study entry](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[If No, please specify the stop date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[Stop date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:50:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 01 Oct 2020 21:54:42 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[Start Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'Jan 1989' | System | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[Start Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered '1989' | System | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[Stop Month and Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 21:58:57

[Stop Year \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered empty. | System | 11 Aug 2020 15:21:29 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '12:58' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered '10 Aug 2020 12:58' | System | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Height \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '171.4' cm | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:16:51 |
| DataPoint set to visible. | (b) (4) System | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Weight (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '64.9' kg | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:16:51 |
| DataPoint set to visible. | (b) (4) System | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

BMI (xxx.x)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| Amendment Manager: User entered '22.09139' | System | 16 Sep 2020 23:50:18 |
| User entered '22.1' | System | 11 Aug 2020 15:16:51 |
| DataPoint set to visible. | System | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[BMI units](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'kg/m2' | System | 11 Aug 2020 15:16:51 |
| DataPoint set to visible. | System | 10 Aug 2020 19:45:38 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for "Not done" and not left empty). Please note that the unit should not remain. Please update accordingly. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 09:19:08 |
| Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for "Not done" and not left empty). Please note that the unit should not remain. Please update accordingly. ' answered with 'updated' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 15:45:10 |
| Signature has been broken. | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 15:45:04 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 15:45:04 |
| User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE on this page (ND for "Not done" and not left empty). Please note that the unit should not remain. Please update accordingly. ' (Site from DM). | (b) (4), (b) (6) | 06 Oct 2020 15:01:03 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '36.8' C | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| Signature has been broken. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 06 Oct 2020 15:45:04 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Kelsey Kelley (b) (4) | 06 Oct 2020 15:45:04 |
| | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| | (b) (4) | |
| User entered 'Oral (Oral)' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:16:51 |
| | (b) (4) | |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 07 Oct 2020 09:19:10 |
| Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' answered with 'updated' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 15:45:15 |
| Signature has been broken. | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 15:45:04 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 15:45:04 |
| User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please update accordingly.' (Site from DM). | (b) (4), (b) (6) | 06 Oct 2020 15:01:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '63' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'bpm' | System | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| Signature has been broken. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 06 Oct 2020 15:45:04 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kelsey Kelley (b) (4) | 06 Oct 2020 15:45:04 |
| | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| | (b) (4) | |
| User entered '14' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:16:51 |
| | (b) (4) | |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'breaths/min' | System | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| Signature has been broken. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 06 Oct 2020 15:45:04 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kelsey Kelley (b) (4) | 06 Oct 2020 15:45:04 |
| | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| | (b) (4) | |
| User entered '110' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:16:51 |
| | (b) (4) | |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'mmHg' | System | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| Signature has been broken. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 06 Oct 2020 15:45:04 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Kelsey Kelley (b) (4) | 06 Oct 2020 15:45:04 |
| | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| | (b) (4) | |
| User entered '76' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:16:51 |
| | (b) (4) | |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User entered 'mmHg' | System | 11 Aug 2020 15:16:51 |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| | | |

US3032171

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| | | |

US3032171

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:39 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:16:57 |

US3032171

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:39 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:16:57 |

US3032171

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:48 |

US3032171

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:57

[Is the participant of childbearing potential?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:48 |

US3032171

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:57

[If No, what is the reason?](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Post-menopausal (POST-MENOPAUSAL)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:48 |

US3032171

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:57

[If Partner medically sterile or Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:48 |

US3032171

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:57

If Surgically sterile, date of surgery (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:48 |

US3032171

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:57

[Date of surgery unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:48 |

US3032171

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:57

If Post-menopausal, date of last menstruation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'un UNK 2018' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:48 |

US3032171

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 21:58:57

[Date of last menstruation unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:51:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:48 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Other

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

No Risk Identified

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

[Resides in Nursing Home or Assisted Living Facility](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

[Resides in a single family home](#) (i.e., detached housing)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'l' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

Other

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 21:58:57

[Specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 04:59:57 |
| DataPoint Verified. | | 02 Dec 2020 19:52:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:15:03 |

US3032171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Illnes Visit Day 1 has only SARS sample collected, however PPD lab reports Immunogenicity sample dated 08SEP2020 under Illness Visit Day 1. Please confirm if an Immunogenicity sample was also collected with the SARS COV2 sample at the Illness Visit Day 28 visit then "Immunogenicity "sample will be recorded under UNSCH visit as there is no Immunogenicity assessment form under Illness visit to record missing data in EDC or else Please confirm that the sample 08SEP2020 is for the SARS Cov2 visit Illness Visit Day and update the Preclarus PPD accordingly for the panel name.' (Site from DM). | | 21 Jan 2021 09:02:39 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Illnes Visit Day 1 has only SARS sample collected, however PPD lab reports Immunogenicity sample dated 08SEP2020 under Illness Visit Day 1. Please confirm if an Immunogenicity sample was also collected with the SARS COV2 sample at the Illness Visit Day 28 visit then "Immunogenicity "sample will be recorded under UNSCH visit as there is no Immunogenicity assessment form under Illness visit to record missing data in EDC or else Please confirm that the sample 08SEP2020 is for the SARS Cov2 visit Illness Visit Day and update the Preclarus PPD accordingly for the panel name.' answered with 'will update accordingly' (Site from DM). | Samantha Wieseler (b) (4) | 19 Jan 2021 22:39:17 |

US3032171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Illnes Visit Day 1 has only SARS sample collected, however PPD lab reports Immunogenicity sample dated 08SEP2020 under Illness Visit Day 1. Please confirm if an Immunogenicity sample was also collected with the SARS COV2 sample at the Illness Visit Day 28 visit then "Immunogenicity "sample will be recorded under UNSCH visit as there is no Immunogenicity assessment form under Illness visit to record missing data in EDC or else Please confirm that the sample 08SEP2020 is for the SARS Cov2 visit Illness Visit Day and update the Preclarus PPD accordingly for the panel name.' (Site from DM). | (b) (4), (b) (6) | 11 Jan 2021 08:02:09 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 15 Dec 2020 06:21:44 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'sample was shipped' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 14 Dec 2020 16:10:39 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is recorded under Unscheduled visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Dec 2020 08:05:39 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 19:52:27 |

US3032171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:42 |

US3032171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:27 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:42 |

US3032171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:27 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Clinic (Clinic)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:42 |

US3032171

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'VISIT1' | System | 11 Aug 2020 15:13:42 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

What was the date of randomization? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 AUG 2020' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Aug 2020 18:49:18 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

What was the participant's randomization number?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System). | (b) (4) | |
| | System | 21 Aug 2020 03:21:11 |
| Amendment Manager: Data point set to conformant. | System | 21 Aug 2020 03:21:11 |
| User opened query 'Data entered is non-conformant. Please correct.' (Site from System). | System | 10 Aug 2020 18:49:18 |
| User entered '102684' (non-conformant). | RWS_ENDPOINT ENDPOINT (b) (4) | 10 Aug 2020 18:49:18 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

[In what Cohort was the participant enrolled?](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '>=18 and <65 years and not at risk (1)' | (b) (4) RWS_ENDPOINT ENDPOINT (b) (4) | 10 Aug 2020 18:49:18 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:54 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:54 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

Severe obesity (body mass index > or = 40kg/m2)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:54 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

[Diabetes \(Type I, Type 2, or gestational\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:54 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

[Liver Disease](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:13:54 |

US3032171

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 21:58:57

Human Immunodeficiency Virus (HIV) infection

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 02 Nov 2020 22:05:23 |
| User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 02 Nov 2020 07:03:31 |
| Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'done' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 29 Oct 2020 16:59:21 |
| User entered 'No (N)' | Kelsey Kelley (b) (4) (b) (4) | 29 Oct 2020 16:59:17 |
| User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 28 Oct 2020 22:35:39 |
| Amendment Manager: DataPoint set to visible. | System | 19 Sep 2020 10:16:45 |
| Amendment Manager inserted this DataPoint. | System | 19 Sep 2020 06:17:14 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

Height

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:35 |
| User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 08:10:13 |
| Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'DATA UPDATED' (Site from DM). | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:21:04 |
| Signature has been broken. | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:20:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:20:57 |
| User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 09:18:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '171.4' cm | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

Weight

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:35 |
| Signature has been broken. | (b) (4) | |
| | Linden DeBoer (b) (4) | 07 Oct 2020 14:20:57 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for | Linden DeBoer (b) (4) | 07 Oct 2020 14:20:57 |
| change Data Entry Error | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| | (b) (4) | |
| User entered '64.9' kg | Kelsey Kelley (b) (4) | 11 Aug 2020 15:18:12 |
| | (b) (4) | |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

Height

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:35 |
| User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 08:10:13 |
| Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'DATA UPDATED' (Site from DM). | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:21:04 |
| Signature has been broken. | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:20:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:20:57 |
| User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 09:18:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '171.4' cm | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

Weight

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:35 |
| Signature has been broken. | (b) (4) | |
| | Linden DeBoer (b) (4) | 07 Oct 2020 14:20:57 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for | Linden DeBoer (b) (4) | 07 Oct 2020 14:20:57 |
| change Data Entry Error | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| | (b) (4) | |
| User entered '64.9' kg | Kelsey Kelley (b) (4) | 11 Aug 2020 15:18:12 |
| | (b) (4) | |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '12:58' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered '10 Aug 2020 12:58' | System | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '36.8' C | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Oral (Oral)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '63' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'bpm' | System | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '14' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'breaths/min' | System | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '110' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'mmHg' | System | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '76' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'mmHg' | System | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

Height

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:35 |
| User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 08:10:13 |
| Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'DATA UPDATED' (Site from DM). | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:21:04 |
| Signature has been broken. | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:20:57 |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 14:20:57 |
| User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM). | (b) (4), (b) (6) | 07 Oct 2020 09:18:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '171.4' cm | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:18:12 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

Weight

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:35 |
| Signature has been broken. | (b) (4) | |
| | Linden DeBoer (b) (4) | 07 Oct 2020 14:20:57 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Linden DeBoer (b) (4) | 07 Oct 2020 14:20:57 |
| | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| | (b) (4) | |
| User entered '64.9' kg | Kelsey Kelley (b) (4) | 11 Aug 2020 15:18:12 |
| | (b) (4) | |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 13 Aug 2020 08:29:01 |
| Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 per protocol' (Site from System). | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:41 |
| User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System). | | 11 Aug 2020 15:19:25 |
| User entered '14:43' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered '10 Aug 2020 14:43' | System | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '36.7' C | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Oral (Oral)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '60' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'bpm' | System | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '16' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'breaths/min' | System | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '116' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'mmHg' | System | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '78' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'mmHg' | System | 11 Aug 2020 15:19:25 |

US3032171

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Was the physical examination performed?

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:52 |
| User closed query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM). | | 11 Nov 2020 04:02:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' answered with 'data updated' (Site from DM). | (b) (4) Linden DeBoer (b) (4) | 10 Nov 2020 14:57:56 |
| Signature has been broken. | (b) (4) Linden DeBoer (b) (4) | 10 Nov 2020 14:57:43 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) (b) (4) | 10 Nov 2020 14:57:43 |
| User opened query 'Per CDM: Per pages 17-18 of CCGs V2.0., when Screening and Visit 1 Day 1 occur on the same day, Was the physical examination performed? is to be recorded as "No" at Visit 1 Day 1. Please update accordingly. ' (Site from DM). | (b) (4), (b) (6) | 06 Nov 2020 16:25:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:19:48 |
| | (b) (4) | |

US3032171

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:52 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Signature has been broken. | (b) (4) | |
| | Linden DeBoer (b) (4) | 10 Nov 2020 14:57:43 |
| | (b) (4) | |
| User entered empty; reason for change Data Entry Error | Linden DeBoer (b) (4) | 10 Nov 2020 14:57:43 |
| | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| | (b) (4) | |
| User entered '10 Aug 2020' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:19:48 |
| | (b) (4) | |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

If No, reason not given

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '14:10' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered '10 Aug 2020 14:10' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:52:58 |
| User entered 'ONCE' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'INTRAMUSCULAR' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:22:56 |

US3032171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:22:56 |

US3032171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '13:30' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:22:56 |

US3032171

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered '10 Aug 2020 13:30' | System | 11 Aug 2020 15:22:56 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:58:57

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '10 Aug 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:57

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:57

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '13:17' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered '10 Aug 2020 13:17' | System | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:57

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:57

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered empty. | System | 11 Aug 2020 15:21:58 |

US3032171

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:53:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:22:23 |

US3032171

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'I' | System | 11 Aug 2020 15:22:23 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:46:57', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9e56b815-d936-4468-a72c-e41a13c7a2b4' User entered 'Yes (Y)' | System | 10 Aug 2020 19:47:43 |
| | System | 10 Aug 2020 19:47:43 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:47:22', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9e56b815-d936-4468-a72c-e41a13c7a2b4' User entered '98.1' | System | 10 Aug 2020 19:47:43 |
| | System | 10 Aug 2020 19:47:43 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:47:33', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9e56b815-d936-4468-a72c-e41a13c7a2b4' | System | 10 Aug 2020 19:47:43 |
| User entered 'No (N)' | System | 10 Aug 2020 19:47:43 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:47:41', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9e56b815-d936-4468-a72c-e41a13c7a2b4' User entered '10 Aug 2020 14:47' | System | 10 Aug 2020 19:47:43 |
| | System | 10 Aug 2020 19:47:43 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 14:30' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 17:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:57:07', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'be47a148-37f4-4df2-85a9-0eaa02184741' User entered 'Yes (Y)' | System | 10 Aug 2020 22:57:28 |
| | System | 10 Aug 2020 22:57:28 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:57:15', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'be47a148-37f4-4df2-85a9-0eaa02184741' User entered '98.2' | System | 10 Aug 2020 22:57:28 |
| | System | 10 Aug 2020 22:57:28 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:57:22', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'be47a148-37f4-4df2-85a9-0eaa02184741' | System | 10 Aug 2020 22:57:28 |
| User entered 'No (N)' | System | 10 Aug 2020 22:57:28 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:57:26', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'be47a148-37f4-4df2-85a9-0eaa02184741' User entered '10 Aug 2020 17:57' | System | 10 Aug 2020 22:57:28 |
| | System | 10 Aug 2020 22:57:28 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 17:55' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '11 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 2' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:57

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:00:53', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '81983708-e8c0-4e8b-98d5-18d2d8098e0c' User entered 'Yes (Y)' | System | 11 Aug 2020 17:01:18 |
| | System | 11 Aug 2020 17:01:18 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:57

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:08', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '81983708-e8c0-4e8b-98d5-18d2d8098e0c' User entered '98.0' | System | 11 Aug 2020 17:01:18 |
| | System | 11 Aug 2020 17:01:18 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:57

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:12', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '81983708-e8c0-4e8b-98d5-18d2d8098e0c' User entered 'No (N)' | System | 11 Aug 2020 17:01:18 |
| | System | 11 Aug 2020 17:01:18 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:15', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '81983708-e8c0-4e8b-98d5-18d2d8098e0c' User entered '11 Aug 2020 12:01' | System | 11 Aug 2020 17:01:18 |
| | System | 11 Aug 2020 17:01:18 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '11 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '12 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 3' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:57

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2167d411-4be3-4b31-829f-2e48b63ff44e' User entered 'Yes (Y)' | System | 12 Aug 2020 17:36:15 |
| | System | 12 Aug 2020 17:36:15 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:57

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:05', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2167d411-4be3-4b31-829f-2e48b63ff44e' User entered '98.8' | System | 12 Aug 2020 17:36:15 |
| | System | 12 Aug 2020 17:36:15 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:57

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:09', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2167d411-4be3-4b31-829f-2e48b63ff44e' User entered 'No (N)' | System | 12 Aug 2020 17:36:15 |
| | System | 12 Aug 2020 17:36:15 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:11', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2167d411-4be3-4b31-829f-2e48b63ff44e' | System | 12 Aug 2020 17:36:15 |
| User entered '12 Aug 2020 12:36' | System | 12 Aug 2020 17:36:15 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '12 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '13 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 4' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:57

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:18', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '38e787ee-aa1a-49dd-a2ec-6ec8c4af4f68' User entered 'Yes (Y)' | System | 13 Aug 2020 17:14:28 |
| | System | 13 Aug 2020 17:14:28 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:57

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:21', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '38e787ee-aa1a-49dd-a2ec-6ec8c4af4f68' User entered '98.6' | System | 13 Aug 2020 17:14:28 |
| | System | 13 Aug 2020 17:14:28 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:57

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:24', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '38e787ee-aa1a-49dd-a2ec-6ec8c4af4f68' | System | 13 Aug 2020 17:14:28 |
| User entered 'No (N)' | System | 13 Aug 2020 17:14:28 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:27', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '38e787ee-aa1a-49dd-a2ec-6ec8c4af4f68' | System | 13 Aug 2020 17:14:28 |
| User entered '13 Aug 2020 12:14' | System | 13 Aug 2020 17:14:28 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '13 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '14 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 5' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:57

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:22', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'bd041325-7a73-4f4d-a84a-b6012334d3c9' User entered 'Yes (Y)' | System | 14 Aug 2020 17:03:22 |
| | System | 14 Aug 2020 17:03:22 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:57

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:27', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'bd041325-7a73-4f4d-a84a-b6012334d3c9' User entered '98.4' | System | 14 Aug 2020 17:03:22 |
| | System | 14 Aug 2020 17:03:22 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:57

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:30', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'bd041325-7a73-4f4d-a84a-b6012334d3c9' User entered 'No (N)' | System | 14 Aug 2020 17:03:22 |
| | System | 14 Aug 2020 17:03:22 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:33', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'bd041325-7a73-4f4d-a84a-b6012334d3c9' User entered '14 Aug 2020 12:02' | System | 14 Aug 2020 17:03:22 |
| | System | 14 Aug 2020 17:03:22 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '14 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '15 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 6' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:57

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:19', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2ed85e2c-5d54-4896-9ee0-edb276a12842' User entered 'Yes (Y)' | System | 15 Aug 2020 17:01:31 |
| | System | 15 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:57

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:24', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2ed85e2c-5d54-4896-9ee0-edb276a12842' User entered '98.1' | System | 15 Aug 2020 17:01:31 |
| | System | 15 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:57

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:27', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2ed85e2c-5d54-4896-9ee0-edb276a12842' | System | 15 Aug 2020 17:01:31 |
| User entered 'No (N)' | System | 15 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:29', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2ed85e2c-5d54-4896-9ee0-edb276a12842' User entered '15 Aug 2020 12:01' | System | 15 Aug 2020 17:01:31 |
| | System | 15 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '15 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '16 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 7' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:57

Was **TEMPERATURE** taken?

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:15:54', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '79e389d1-6f3e-456a-a246-72887d1d6639' User entered 'Yes (Y)' | System | 16 Aug 2020 17:16:07 |
| | System | 16 Aug 2020 17:16:07 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:57

Please record your **TEMPERATURE** in °F

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:15:58', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '79e389d1-6f3e-456a-a246-72887d1d6639' User entered '97.7' | System | 16 Aug 2020 17:16:07 |
| | System | 16 Aug 2020 17:16:07 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:57

Was any **MEDICATION TAKEN** today for pain or fever?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:01', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '79e389d1-6f3e-456a-a246-72887d1d6639' User entered 'No (N)' | System | 16 Aug 2020 17:16:07 |
| | System | 16 Aug 2020 17:16:07 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:04', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '79e389d1-6f3e-456a-a246-72887d1d6639' User entered '16 Aug 2020 12:16' | System | 16 Aug 2020 17:16:07 |
| | System | 16 Aug 2020 17:16:07 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '16 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '17 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:03', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e55096c2-b602-4520-85fe-2fca1e2fc048' | System | 10 Aug 2020 19:48:34 |
| User entered 'Does not interfere with activity (2)' | System | 10 Aug 2020 19:48:34 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:16', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e55096c2-b602-4520-85fe-2fca1e2fc048' | System | 10 Aug 2020 19:48:34 |
| User entered 'No (N)' | System | 10 Aug 2020 19:48:34 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:22', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e55096c2-b602-4520-85fe-2fca1e2fc048' | System | 10 Aug 2020 19:48:34 |
| User entered 'No (N)' | System | 10 Aug 2020 19:48:34 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:28', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e55096c2-b602-4520-85fe-2fca1e2fc048' | System | 10 Aug 2020 19:48:34 |
| User entered 'None (1)' | System | 10 Aug 2020 19:48:34 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:31', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e55096c2-b602-4520-85fe-2fca1e2fc048' User entered '10 Aug 2020 14:48' | System | 10 Aug 2020 19:48:34 |
| | System | 10 Aug 2020 19:48:34 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 14:30' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 17:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:56:17', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '5d5ca214-84c0-4100-b34b-0b1bbeccb2f8' User entered 'None (1)' | System | 10 Aug 2020 22:56:41 |
| | System | 10 Aug 2020 22:56:41 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:56:24', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '5d5ca214-84c0-4100-b34b-0b1bbeccb2f8' User entered 'No (N)' | System | 10 Aug 2020 22:56:41 |
| | System | 10 Aug 2020 22:56:41 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:56:26', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '5d5ca214-84c0-4100-b34b-0b1bbeccb2f8' User entered 'No (N)' | System | 10 Aug 2020 22:56:41 |
| | System | 10 Aug 2020 22:56:41 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:56:32', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '5d5ca214-84c0-4100-b34b-0b1bbeccb2f8' | System | 10 Aug 2020 22:56:41 |
| User entered 'None (1)' | System | 10 Aug 2020 22:56:41 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:56:38', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '5d5ca214-84c0-4100-b34b-0b1bbeccb2f8' User entered '10 Aug 2020 17:56' | System | 10 Aug 2020 22:56:41 |
| | System | 10 Aug 2020 22:56:41 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 17:55' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '11 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 2' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:19', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8e0a54e3-2667-42b1-ac8e-549ab109dafd' User entered 'None (1)' | System | 11 Aug 2020 17:01:31 |
| | System | 11 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:22', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8e0a54e3-2667-42b1-ac8e-549ab109dafd' User entered 'No (N)' | System | 11 Aug 2020 17:01:31 |
| | System | 11 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:25', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8e0a54e3-2667-42b1-ac8e-549ab109dafd' User entered 'No (N)' | System | 11 Aug 2020 17:01:31 |
| | System | 11 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:27', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8e0a54e3-2667-42b1-ac8e-549ab109dafd' User entered 'None (1)' | System | 11 Aug 2020 17:01:31 |
| | System | 11 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:29', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8e0a54e3-2667-42b1-ac8e-549ab109dafd' User entered '11 Aug 2020 12:01' | System | 11 Aug 2020 17:01:31 |
| | System | 11 Aug 2020 17:01:31 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '11 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '12 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 3' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:14', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '893ff1d6-b27d-463d-89d1-051e348d6819' User entered 'None (1)' | System | 12 Aug 2020 17:36:26 |
| | System | 12 Aug 2020 17:36:26 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:17', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '893ff1d6-b27d-463d-89d1-051e348d6819' User entered 'No (N)' | System | 12 Aug 2020 17:36:26 |
| | System | 12 Aug 2020 17:36:26 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:19', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '893ff1d6-b27d-463d-89d1-051e348d6819' User entered 'No (N)' | System | 12 Aug 2020 17:36:26 |
| | System | 12 Aug 2020 17:36:26 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:21', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '893ff1d6-b27d-463d-89d1-051e348d6819' User entered 'None (1)' | System | 12 Aug 2020 17:36:26 |
| | System | 12 Aug 2020 17:36:26 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:36:23', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '893ff1d6-b27d-463d-89d1-051e348d6819' User entered '12 Aug 2020 12:36' | System | 12 Aug 2020 17:36:26 |
| | System | 12 Aug 2020 17:36:26 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '12 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '13 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 4' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:30', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '7c1d4d65-2843-4ca3-be0b-7955a0e5752d' User entered 'None (1)' | System | 13 Aug 2020 17:14:45 |
| | System | 13 Aug 2020 17:14:45 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:33', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '7c1d4d65-2843-4ca3-be0b-7955a0e5752d' User entered 'No (N)' | System | 13 Aug 2020 17:14:45 |
| | System | 13 Aug 2020 17:14:45 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:35', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '7c1d4d65-2843-4ca3-be0b-7955a0e5752d' User entered 'No (N)' | System | 13 Aug 2020 17:14:45 |
| | System | 13 Aug 2020 17:14:45 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:37', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '7c1d4d65-2843-4ca3-be0b-7955a0e5752d' User entered 'None (1)' | System | 13 Aug 2020 17:14:45 |
| | System | 13 Aug 2020 17:14:45 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:42', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '7c1d4d65-2843-4ca3-be0b-7955a0e5752d' User entered '13 Aug 2020 12:14' | System | 13 Aug 2020 17:14:45 |
| | System | 13 Aug 2020 17:14:45 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '13 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '14 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 5' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:36', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aea4830b-8680-4a96-b3e3-d7d479a217ca' User entered 'None (1)' | System | 14 Aug 2020 17:03:29 |
| | System | 14 Aug 2020 17:03:29 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:38', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aea4830b-8680-4a96-b3e3-d7d479a217ca' User entered 'No (N)' | System | 14 Aug 2020 17:03:29 |
| | System | 14 Aug 2020 17:03:29 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:43', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aea4830b-8680-4a96-b3e3-d7d479a217ca' User entered 'No (N)' | System | 14 Aug 2020 17:03:29 |
| | System | 14 Aug 2020 17:03:29 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:45', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aea4830b-8680-4a96-b3e3-d7d479a217ca' User entered 'None (1)' | System | 14 Aug 2020 17:03:29 |
| | System | 14 Aug 2020 17:03:29 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:47', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aea4830b-8680-4a96-b3e3-d7d479a217ca' User entered '14 Aug 2020 12:02' | System | 14 Aug 2020 17:03:29 |
| | System | 14 Aug 2020 17:03:29 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '14 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '15 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 6' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:32', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9cb298b9-0888-4c52-8746-a33373d29d89' | System | 15 Aug 2020 17:01:42 |
| User entered 'None (1)' | System | 15 Aug 2020 17:01:42 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

Is there any **REDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:35', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9cb298b9-0888-4c52-8746-a33373d29d89' User entered 'No (N)' | System | 15 Aug 2020 17:01:42 |
| | System | 15 Aug 2020 17:01:42 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:37', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9cb298b9-0888-4c52-8746-a33373d29d89' User entered 'No (N)' | System | 15 Aug 2020 17:01:42 |
| | System | 15 Aug 2020 17:01:42 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:38', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9cb298b9-0888-4c52-8746-a33373d29d89' | System | 15 Aug 2020 17:01:42 |
| User entered 'None (1)' | System | 15 Aug 2020 17:01:42 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:41', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9cb298b9-0888-4c52-8746-a33373d29d89' User entered '15 Aug 2020 12:01' | System | 15 Aug 2020 17:01:42 |
| | System | 15 Aug 2020 17:01:42 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '15 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '16 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 7' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:07', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1bde4dd6-799c-4ad2-ad8d-2dc3f4c54b2d' User entered 'None (1)' | System | 16 Aug 2020 17:16:17 |
| | System | 16 Aug 2020 17:16:17 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

Is there any REDNESS AT INJECTION SITE?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:09', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1bde4dd6-799c-4ad2-ad8d-2dc3f4c54b2d' User entered 'No (N)' | System | 16 Aug 2020 17:16:17 |
| | System | 16 Aug 2020 17:16:17 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:10', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1bde4dd6-799c-4ad2-ad8d-2dc3f4c54b2d' User entered 'No (N)' | System | 16 Aug 2020 17:16:17 |
| | System | 16 Aug 2020 17:16:17 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:12', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1bde4dd6-799c-4ad2-ad8d-2dc3f4c54b2d' User entered 'None (1)' | System | 16 Aug 2020 17:16:17 |
| | System | 16 Aug 2020 17:16:17 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Time Stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:14', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1bde4dd6-799c-4ad2-ad8d-2dc3f4c54b2d' User entered '16 Aug 2020 12:16' | System | 16 Aug 2020 17:16:17 |
| | System | 16 Aug 2020 17:16:17 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '16 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '17 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 1, 30 Minutes after vaccination (at study clinic)' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:36', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2b2dbcf4-4bd8-4cda-920c-e49f1a6647b8' User entered 'None (0)' | System | 10 Aug 2020 19:49:00 |
| | System | 10 Aug 2020 19:49:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:39', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2b2dbcf4-4bd8-4cda-920c-e49f1a6647b8' User entered 'None (0)' | System | 10 Aug 2020 19:49:00 |
| | System | 10 Aug 2020 19:49:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:42', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2b2dbcf4-4bd8-4cda-920c-e49f1a6647b8' User entered 'None (0)' | System | 10 Aug 2020 19:49:00 |
| | System | 10 Aug 2020 19:49:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:45', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2b2dbcf4-4bd8-4cda-920c-e49f1a6647b8' User entered 'None (0)' | System | 10 Aug 2020 19:49:00 |
| | System | 10 Aug 2020 19:49:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:47', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2b2dbcf4-4bd8-4cda-920c-e49f1a6647b8' User entered 'None (0)' | System | 10 Aug 2020 19:49:00 |
| | System | 10 Aug 2020 19:49:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:49', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2b2dbcf4-4bd8-4cda-920c-e49f1a6647b8' User entered 'None (0)' | System | 10 Aug 2020 19:49:00 |
| | System | 10 Aug 2020 19:49:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:55', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2b2dbcf4-4bd8-4cda-920c-e49f1a6647b8' User entered 'No (N)' | System | 10 Aug 2020 19:49:00 |
| | System | 10 Aug 2020 19:49:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T14:48:59', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2b2dbcf4-4bd8-4cda-920c-e49f1a6647b8' User entered '10 Aug 2020 14:48' | System | 10 Aug 2020 19:49:00 |
| | System | 10 Aug 2020 19:49:00 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 14:30' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 17:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 1, after vaccination (at home)' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:55:42', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '3e85fe5e-72b5-4ac3-86af-1b929485ce13' User entered 'None (0)' | System | 10 Aug 2020 22:56:10 |
| | System | 10 Aug 2020 22:56:10 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:55:45', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '3e85fe5e-72b5-4ac3-86af-1b929485ce13' User entered 'None (0)' | System | 10 Aug 2020 22:56:10 |
| | System | 10 Aug 2020 22:56:10 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:55:48', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '3e85fe5e-72b5-4ac3-86af-1b929485ce13' User entered 'None (0)' | System | 10 Aug 2020 22:56:10 |
| | System | 10 Aug 2020 22:56:10 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:55:51', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '3e85fe5e-72b5-4ac3-86af-1b929485ce13' User entered 'None (0)' | System | 10 Aug 2020 22:56:10 |
| | System | 10 Aug 2020 22:56:10 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:55:54', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '3e85fe5e-72b5-4ac3-86af-1b929485ce13' User entered 'None (0)' | System | 10 Aug 2020 22:56:10 |
| | System | 10 Aug 2020 22:56:10 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:55:56', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '3e85fe5e-72b5-4ac3-86af-1b929485ce13' User entered 'None (0)' | System | 10 Aug 2020 22:56:10 |
| | System | 10 Aug 2020 22:56:10 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:56:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '3e85fe5e-72b5-4ac3-86af-1b929485ce13' User entered 'No (N)' | System | 10 Aug 2020 22:56:10 |
| | System | 10 Aug 2020 22:56:10 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-10T17:56:08', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '3e85fe5e-72b5-4ac3-86af-1b929485ce13' User entered '10 Aug 2020 17:56' | System | 10 Aug 2020 22:56:10 |
| | System | 10 Aug 2020 22:56:10 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '10 Aug 2020 17:55' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '11 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 2' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:32', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'caaac5f8-f908-44e8-a932-5570ec6c1d0f' User entered 'None (0)' | System | 11 Aug 2020 17:01:50 |
| | System | 11 Aug 2020 17:01:50 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:34', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'caaac5f8-f908-44e8-a932-5570ec6c1d0f' User entered 'None (0)' | System | 11 Aug 2020 17:01:50 |
| | System | 11 Aug 2020 17:01:50 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:36', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'caaac5f8-f908-44e8-a932-5570ec6c1d0f' User entered 'None (0)' | System | 11 Aug 2020 17:01:50 |
| | System | 11 Aug 2020 17:01:50 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:37', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'caaac5f8-f908-44e8-a932-5570ec6c1d0f' User entered 'None (0)' | System | 11 Aug 2020 17:01:50 |
| | System | 11 Aug 2020 17:01:50 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:40', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'caaac5f8-f908-44e8-a932-5570ec6c1d0f' User entered 'None (0)' | System | 11 Aug 2020 17:01:50 |
| | System | 11 Aug 2020 17:01:50 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:41', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'caaac5f8-f908-44e8-a932-5570ec6c1d0f' User entered 'None (0)' | System | 11 Aug 2020 17:01:50 |
| | System | 11 Aug 2020 17:01:50 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:45', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'caaac5f8-f908-44e8-a932-5570ec6c1d0f' User entered 'No (N)' | System | 11 Aug 2020 17:01:50 |
| | System | 11 Aug 2020 17:01:50 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-11T12:01:48', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'caaac5f8-f908-44e8-a932-5570ec6c1d0f' User entered '11 Aug 2020 12:01' | System | 11 Aug 2020 17:01:50 |
| | System | 11 Aug 2020 17:01:50 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '11 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '12 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 3' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:35:22', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '84f30b51-2067-4bce-bb84-e245de0f7453' User entered 'None (0)' | System | 12 Aug 2020 17:35:40 |
| | System | 12 Aug 2020 17:35:40 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:35:24', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '84f30b51-2067-4bce-bb84-e245de0f7453' User entered 'None (0)' | System | 12 Aug 2020 17:35:40 |
| | System | 12 Aug 2020 17:35:40 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:35:25', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '84f30b51-2067-4bce-bb84-e245de0f7453' User entered 'None (0)' | System | 12 Aug 2020 17:35:40 |
| | System | 12 Aug 2020 17:35:40 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:35:27', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '84f30b51-2067-4bce-bb84-e245de0f7453' User entered 'None (0)' | System | 12 Aug 2020 17:35:40 |
| | System | 12 Aug 2020 17:35:40 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:35:28', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '84f30b51-2067-4bce-bb84-e245de0f7453' User entered 'None (0)' | System | 12 Aug 2020 17:35:40 |
| | System | 12 Aug 2020 17:35:40 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:35:33', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '84f30b51-2067-4bce-bb84-e245de0f7453' User entered 'None (0)' | System | 12 Aug 2020 17:35:40 |
| | System | 12 Aug 2020 17:35:40 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:35:36', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '84f30b51-2067-4bce-bb84-e245de0f7453' User entered 'No (N)' | System | 12 Aug 2020 17:35:40 |
| | System | 12 Aug 2020 17:35:40 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-12T12:35:38', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '84f30b51-2067-4bce-bb84-e245de0f7453' | System | 12 Aug 2020 17:35:40 |
| User entered '12 Aug 2020 12:35' | System | 12 Aug 2020 17:35:40 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '12 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '13 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 4' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:45', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9b8ae364-8a50-4c21-91ba-b40209cae877' | System | 13 Aug 2020 17:15:04 |
| User entered 'None (0)' | System | 13 Aug 2020 17:15:04 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:46', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9b8ae364-8a50-4c21-91ba-b40209cae877' User entered 'None (0)' | System | 13 Aug 2020 17:15:04 |
| | System | 13 Aug 2020 17:15:04 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:47', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9b8ae364-8a50-4c21-91ba-b40209cae877' User entered 'None (0)' | System | 13 Aug 2020 17:15:04 |
| | System | 13 Aug 2020 17:15:04 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:49', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9b8ae364-8a50-4c21-91ba-b40209cae877' User entered 'None (0)' | System | 13 Aug 2020 17:15:04 |
| | System | 13 Aug 2020 17:15:04 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:51', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9b8ae364-8a50-4c21-91ba-b40209cae877' User entered 'None (0)' | System | 13 Aug 2020 17:15:04 |
| | System | 13 Aug 2020 17:15:04 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:53', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9b8ae364-8a50-4c21-91ba-b40209cae877' User entered 'None (0)' | System | 13 Aug 2020 17:15:04 |
| | System | 13 Aug 2020 17:15:04 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:14:55', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9b8ae364-8a50-4c21-91ba-b40209cae877' | System | 13 Aug 2020 17:15:04 |
| User entered 'No (N)' | System | 13 Aug 2020 17:15:04 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-13T12:15:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '9b8ae364-8a50-4c21-91ba-b40209cae877' | System | 13 Aug 2020 17:15:04 |
| User entered '13 Aug 2020 12:15' | System | 13 Aug 2020 17:15:04 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '13 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '14 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 5' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:51', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f0c43890-f183-4a7b-900e-21d41bbdbe13' User entered 'None (0)' | System | 14 Aug 2020 17:03:44 |
| | System | 14 Aug 2020 17:03:44 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:54', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f0c43890-f183-4a7b-900e-21d41bbdbe13' User entered 'None (0)' | System | 14 Aug 2020 17:03:44 |
| | System | 14 Aug 2020 17:03:44 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:56', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f0c43890-f183-4a7b-900e-21d41bbdbe13' User entered 'None (0)' | System | 14 Aug 2020 17:03:44 |
| | System | 14 Aug 2020 17:03:44 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:02:58', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f0c43890-f183-4a7b-900e-21d41bbdbe13' User entered 'None (0)' | System | 14 Aug 2020 17:03:44 |
| | System | 14 Aug 2020 17:03:44 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:03:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f0c43890-f183-4a7b-900e-21d41bbdbe13' User entered 'None (0)' | System | 14 Aug 2020 17:03:44 |
| | System | 14 Aug 2020 17:03:44 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:03:02', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f0c43890-f183-4a7b-900e-21d41bbdbe13' User entered 'None (0)' | System | 14 Aug 2020 17:03:44 |
| | System | 14 Aug 2020 17:03:44 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:03:05', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f0c43890-f183-4a7b-900e-21d41bbdbe13' User entered 'No (N)' | System | 14 Aug 2020 17:03:44 |
| | System | 14 Aug 2020 17:03:44 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-14T12:03:07', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f0c43890-f183-4a7b-900e-21d41bbdbe13' User entered '14 Aug 2020 12:03' | System | 14 Aug 2020 17:03:44 |
| | System | 14 Aug 2020 17:03:44 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '14 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '15 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 6' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:44', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '684308ff-eafa-46fc-b18a-a8194e193a9d' User entered 'None (0)' | System | 15 Aug 2020 17:01:59 |
| | System | 15 Aug 2020 17:01:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:45', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '684308ff-eafa-46fc-b18a-a8194e193a9d' User entered 'None (0)' | System | 15 Aug 2020 17:01:59 |
| | System | 15 Aug 2020 17:01:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:47', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '684308ff-eafa-46fc-b18a-a8194e193a9d' User entered 'None (0)' | System | 15 Aug 2020 17:01:59 |
| | System | 15 Aug 2020 17:01:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:48', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '684308ff-eafa-46fc-b18a-a8194e193a9d' User entered 'None (0)' | System | 15 Aug 2020 17:01:59 |
| | System | 15 Aug 2020 17:01:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:50', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '684308ff-eafa-46fc-b18a-a8194e193a9d' User entered 'None (0)' | System | 15 Aug 2020 17:01:59 |
| | System | 15 Aug 2020 17:01:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:51', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '684308ff-eafa-46fc-b18a-a8194e193a9d' User entered 'None (0)' | System | 15 Aug 2020 17:01:59 |
| | System | 15 Aug 2020 17:01:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:54', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '684308ff-eafa-46fc-b18a-a8194e193a9d' User entered 'No (N)' | System | 15 Aug 2020 17:01:59 |
| | System | 15 Aug 2020 17:01:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-15T12:01:56', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '684308ff-eafa-46fc-b18a-a8194e193a9d' User entered '15 Aug 2020 12:01' | System | 15 Aug 2020 17:01:59 |
| | System | 15 Aug 2020 17:01:59 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '15 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '16 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 7' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

HEADACHE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:19', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '4b20d511-4459-4ed2-81d9-898cb025cffb' User entered 'None (0)' | System | 16 Aug 2020 17:16:35 |
| | System | 16 Aug 2020 17:16:35 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

FATIGUE

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:21', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '4b20d511-4459-4ed2-81d9-898cb025cffb' User entered 'None (0)' | System | 16 Aug 2020 17:16:35 |
| | System | 16 Aug 2020 17:16:35 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

MUSCLE ACHES ALL OVER BODY

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:22', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '4b20d511-4459-4ed2-81d9-898cb025cffb' User entered 'None (0)' | System | 16 Aug 2020 17:16:35 |
| | System | 16 Aug 2020 17:16:35 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

JOINT ACHES IN SEVERAL JOINTS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:24', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '4b20d511-4459-4ed2-81d9-898cb025cffb' User entered 'None (0)' | System | 16 Aug 2020 17:16:35 |
| | System | 16 Aug 2020 17:16:35 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

NAUSEA/VOMITING

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:25', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '4b20d511-4459-4ed2-81d9-898cb025cffb' User entered 'None (0)' | System | 16 Aug 2020 17:16:35 |
| | System | 16 Aug 2020 17:16:35 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

CHILLS

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:27', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '4b20d511-4459-4ed2-81d9-898cb025cffb' User entered 'None (0)' | System | 16 Aug 2020 17:16:35 |
| | System | 16 Aug 2020 17:16:35 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:30', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '4b20d511-4459-4ed2-81d9-898cb025cffb' User entered 'No (N)' | System | 16 Aug 2020 17:16:35 |
| | System | 16 Aug 2020 17:16:35 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Time stamp](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-08-16T12:16:32', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '4b20d511-4459-4ed2-81d9-898cb025cffb' User entered '16 Aug 2020 12:16' | System | 16 Aug 2020 17:16:35 |
| | System | 16 Aug 2020 17:16:35 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '16 Aug 2020 12:00' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 21:58:57

[PC Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| User entered '17 Aug 2020 11:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:54:34 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Aug 2020 18:58:04 |

US3032171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:54:34 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | (b) (4) (b) (4), (b) (6) | 24 Aug 2020 06:40:36 |
| Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'data correct as entered' (Site from System). | Kelsey Kelley (b) (4) (b) (4) | 21 Aug 2020 18:58:15 |
| User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System). | System | 21 Aug 2020 18:58:04 |
| User entered '21 Aug 2020' | Kelsey Kelley (b) (4) (b) (4) | 21 Aug 2020 18:58:04 |

US3032171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:54:34 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Aug 2020 18:58:04 |

US3032171

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:54:34 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Aug 2020 18:58:04 |

US3032171

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:54:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Aug 2020 18:58:19 |

US3032171

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'I' | System | 21 Aug 2020 18:58:19 |

US3032171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:05 |

US3032171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '24 Aug 2020' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:05 |

US3032171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:05 |

US3032171

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:05 |

US3032171

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:14 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:11 |

US3032171

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 Apr 2021 08:02:25 |
| User entered 'I' | System | 08 Sep 2020 16:47:11 |

US3032171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:22:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:48 |

US3032171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:22:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '31 Aug 2020' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:48 |

US3032171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:22:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:48 |

US3032171

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:22:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:48 |

US3032171

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:22:25 |
| DataPoint Verified. | | 02 Dec 2020 19:55:36 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:47:55 |

US3032171

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 07:22:25 |
| User entered 'I' | System | 08 Sep 2020 16:47:55 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:56:53 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 08sep2020 is reported under "Unscheduled visit" in PPD Central lab Immuno, however the "Immunogenicity Assessment" page under the folder "Unscheduled 08sep2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 08sep2020 visit. ' (Site from DM). | | 25 Nov 2020 04:45:25 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 08sep2020 is reported under "Unscheduled visit" in PPD Central lab Immuno, however the "Immunogenicity Assessment" page under the folder "Unscheduled 08sep2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 08sep2020 visit. ' answered with 'IMMUNOGENICITY ASSESSMENT FORM IS COMPLETED FOR 08 SEP UNDER ILLNESS VISIT DAY 1.' (Site from DM). | Russell Herstein (b) (4) (b) (4) | 19 Nov 2020 21:49:43 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity Re-query : Sample dated 08sep2020 is reported under "Unscheduled visit" in PPD Central lab Immuno, however the "Immunogenicity Assessment" page under the folder "Unscheduled 08sep2020" is missing in EDC Please review if the sample has been collected then update the details under appropriate Unscheduled 08sep2020 visit. ' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 15:52:06 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08sep2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 08sep2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 11:24:24 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08sep2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 08sep2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' answered with 'illness visit is already added' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 10 Nov 2020 20:43:18 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08sep2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 08sep2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' (Site from DM). | (b) (4), (b) (6) (b) (4) | 10 Nov 2020 12:12:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:45:34 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

Visit date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:56:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 03:18:49 |
| Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'data correct as entered' (Site from System). | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:45:50 |
| User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System). | System | 21 Sep 2020 19:45:34 |
| User entered '21 Sep 2020' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:45:34 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:56:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Clinic (Clinic)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:45:34 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'VISIT2' | System | 21 Sep 2020 19:45:34 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '21 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '12:25' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered '21 Sep 2020 12:25' | System | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '37.0' C | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Oral (Oral)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '79' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'bpm' | System | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '14' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'breaths/min' | System | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '107' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'mmHg' | System | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '74' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure units

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'mmHg' | System | 21 Sep 2020 19:46:31 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:08 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:41 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:25 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:58:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '21 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:25 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Confirmed COVID-19 (COVID)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:12 |
| User entered empty. | System | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

What was the route of administration for the study treatment?

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:35 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:34 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:04 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:34 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08SEP2020 is present in GCL for V2D29, but data not present in EDC, please clarify or reconcile' (Site from DM). | | 19 Nov 2020 11:23:01 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08SEP2020 is present in GCL for V2D29, but data not present in EDC, please clarify or reconcile' answered with '08/Sep/2020 was date of first illness visit' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 11 Nov 2020 17:49:07 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 08SEP2020 is present in GCL for V2D29, but data not present in EDC, please clarify or reconcile' (Site from DM). | (b) (4), (b) (6) | 02 Nov 2020 18:14:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '21 Sep 2020' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:04 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

Collection time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:34 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '13:03' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:04 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered '21 Sep 2020 13:03' | System | 21 Sep 2020 19:47:04 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 21:58:57

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '21 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:57

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:57

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered '12:37' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered '21 Sep 2020 12:37' | System | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:57

[Lab Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:57

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 19:59:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered empty. | System | 21 Sep 2020 19:47:13 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Apr 2021 00:11:25 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:52 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:47:16 |

US3032171

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'I' | System | 21 Sep 2020 19:47:16 |

US3032171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:00:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:29:57 |

US3032171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:00:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '28 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:29:57 |

US3032171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:00:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:29:57 |

US3032171

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:00:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:29:57 |

US3032171

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:00:24 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:30:00 |

US3032171

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'I' | System | 19 Oct 2020 20:30:00 |

US3032171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:01:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:30:10 |

US3032171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:01:20 |
| User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 06OCT2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM). | | 19 Nov 2020 11:21:29 |
| Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 06OCT2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' answered with 'this collection was for Convalescence Visit Day 28 on 06OCT2020' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 19:48:46 |
| User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 06OCT2020, however this date is not presently recorded in the CRF. Please clarify if an Unscheduled visit should be added for the subject and update as appropriate.' (Site from DM). | (b) (4), (b) (6) | 24 Oct 2020 00:31:40 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '5 Oct 2020' | Kelsey Kelley (b) (4) | 19 Oct 2020 20:30:10 |

US3032171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:01:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:30:10 |

US3032171

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:01:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:30:10 |

US3032171

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:01:26 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:30:38 |

US3032171

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'I' | System | 19 Oct 2020 20:30:38 |

US3032171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:03:16 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:31:25 |

US3032171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:03:16 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '12 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:31:25 |

US3032171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:03:16 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:31:25 |

US3032171

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:03:16 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:31:25 |

US3032171

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:03:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:31:49 |

US3032171

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered '1' | System | 19 Oct 2020 20:31:49 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User closed query 'Per GCL Lab Reconciliation Requery: Immunogenicity: Thank you for the response "will update accordingly" Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, if the sample was collected then please initiate an 'Unscheduled visit' using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 06oct2020 present in PPD and after update route back to DM route.' (Site from DM). | | 22 Jan 2021 10:41:29 |
| Query 'Per GCL Lab Reconciliation Requery: Immunogenicity: Thank you for the response "will update accordingly" Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, if the sample was collected then please initiate an 'Unscheduled visit' using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 06oct2020 present in PPD and after update route back to DM route.' answered with 'will update accordingly as should be visit 3 not unscheduled' (Site from DM). | Samantha Wieseler (b) (4) | 20 Jan 2021 22:23:14 |
| User opened query 'Per GCL Lab Reconciliation Requery: Immunogenicity: Thank you for the response "will update accordingly" Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, if the sample was collected then please initiate an 'Unscheduled visit' using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 06oct2020 present in PPD and after update route back to DM route.' (Site from DM). | (b) (4), (b) (6) | 20 Jan 2021 12:55:20 |
| User closed query 'Per GCL Lab Reconciliation Requery: Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, Per your response, if the sample was collected then please initiate an 'Unscheduled visit' using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 06oct2020 present in PPD.' (Site from DM). | (b) (4), (b) (6) | 20 Jan 2021 12:53:29 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|--|--|
| Query 'Per GCL Lab Reconciliation Requery: Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, Per your response, if the sample was collected then please initiate an 'Unscheduled visit' using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 06oct2020 present in PPD.' answered with 'will update accordingly' (Site from DM). User opened query 'Per GCL Lab Reconciliation Requery: Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, Per your response, if the sample was collected then please initiate an 'Unscheduled visit' using ADD EVENT option and record the Unscheduled Immunogenicity sample dated 06oct2020 present in PPD.' (Site from DM). DataPoint Verified. | Samantha Wieseler (b) (4) (b) (4) (b) (4), (b) (6) (b) (4), (b) (6) | 19 Jan 2021 22:40:12 15 Dec 2020 07:22:57 02 Dec 2020 20:03:46 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 06oct2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' (Site from DM). | | 19 Nov 2020 11:27:24 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 06oct2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' answered with 'Convalescence visit already recorded under illness visits' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 10 Nov 2020 20:46:01 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 06oct2020 is reported under Unscheduled visit in PPD Central lab, however the Unscheduled 06oct2020 is missing in EDC. Please review if the sample has been collected then update the details under appropriate Unscheduled visit. Else clarify, thank you' (Site from DM). User signature succeeded. | (b) (4), (b) (6) (b) (4) | 10 Nov 2020 12:13:31 |
| | Keith Vrbicky (b) (4) (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:00 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:03:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '19 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:00 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:03:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Clinic (Clinic)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:00 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'VISIT3' | System | 19 Oct 2020 20:32:00 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '19 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '10:10' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered '19 Oct 2020 10:10' | System | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '37.0' C | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Oral (Oral)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '74' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'bpm' | System | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '14' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'breaths/min' | System | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '96' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'mmHg' | System | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | (b) (4) (b) (4), (b) (6) | 20 Oct 2020 10:43:07 |
| Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System). | Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:33:28 |
| User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). | | 19 Oct 2020 20:32:30 |
| User entered '56' | Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'mmHg' | System | 19 Oct 2020 20:32:30 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| | | |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| | | |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:15 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:33:36 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:15 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '19 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:33:36 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:33:54 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '19 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:33:54 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '10:18' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:33:54 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered '19 Oct 2020 10:18' | System | 19 Oct 2020 20:33:54 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| DataPoint Verified. | | 02 Dec 2020 20:04:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:34:09 |

US3032171

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered '1' | System | 19 Oct 2020 20:34:09 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 64' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-12T12:00:32', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f8e98b01-c508-4bc2-8e13-fb7a021b1c87' | System | 12 Oct 2020 17:01:29 |
| User entered 'No (N)' | System | 12 Oct 2020 17:01:29 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-12T12:00:38', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f8e98b01-c508-4bc2-8e13-fb7a021b1c87' | System | 12 Oct 2020 17:01:29 |
| User entered 'No (N)' | System | 12 Oct 2020 17:01:29 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-12T12:00:41', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'f8e98b01-c508-4bc2-8e13-fb7a021b1c87' User entered '12 Oct 2020 12:00:41' | System | 12 Oct 2020 17:01:29 |
| | System | 12 Oct 2020 17:01:29 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '10 Oct 2020 00:01' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '14 Oct 2020 23:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 71' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-17T06:46:16', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8a594de2-953f-4c88-b79c-944b8e4ce659' | System | 17 Oct 2020 11:46:33 |
| User entered 'No (N)' | System | 17 Oct 2020 11:46:33 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-17T06:46:26', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8a594de2-953f-4c88-b79c-944b8e4ce659' | System | 17 Oct 2020 11:46:33 |
| User entered 'No (N)' | System | 17 Oct 2020 11:46:33 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-17T06:46:29', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8a594de2-953f-4c88-b79c-944b8e4ce659' User entered '17 Oct 2020 06:46:29' | System | 17 Oct 2020 11:46:33 |
| | System | 17 Oct 2020 11:46:33 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '17 Oct 2020 00:01' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '21 Oct 2020 23:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 78' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-24T06:59:37', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'ee233144-3794-440c-b432-39fe0b99d532' | System | 24 Oct 2020 11:59:47 |
| User entered 'No (N)' | System | 24 Oct 2020 11:59:47 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-24T06:59:41', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'ee233144-3794-440c-b432-39fe0b99d532' | System | 24 Oct 2020 11:59:47 |
| User entered 'No (N)' | System | 24 Oct 2020 11:59:47 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-10-24T06:59:44', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'ee233144-3794-440c-b432-39fe0b99d532' User entered '24 Oct 2020 06:59:44' | System | 24 Oct 2020 11:59:47 |
| | System | 24 Oct 2020 11:59:47 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '24 Oct 2020 00:01' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '28 Oct 2020 23:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 92' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-07T06:36:09', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '41c3b440-e678-4105-a9d1-d6b9c74d8f49' | System | 07 Nov 2020 12:36:23 |
| User entered 'No (N)' | System | 07 Nov 2020 12:36:23 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-07T06:36:17', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '41c3b440-e678-4105-a9d1-d6b9c74d8f49' | System | 07 Nov 2020 12:36:23 |
| User entered 'No (N)' | System | 07 Nov 2020 12:36:23 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-07T06:36:21', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '41c3b440-e678-4105-a9d1-d6b9c74d8f49' User entered '07 Nov 2020 06:36:21' | System | 07 Nov 2020 12:36:23 |
| | System | 07 Nov 2020 12:36:23 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '07 Nov 2020 00:01' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '11 Nov 2020 23:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered 'Day 99' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-14T06:10:58', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'debfcd44-973f-4aad-b13b-e92982325848' | System | 14 Nov 2020 12:11:07 |
| User entered 'No (N)' | System | 14 Nov 2020 12:11:07 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-14T06:11:02', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'debfcd44-973f-4aad-b13b-e92982325848' | System | 14 Nov 2020 12:11:07 |
| User entered 'No (N)' | System | 14 Nov 2020 12:11:07 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|---|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-14T06:11:05', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'debfc44-973f-4aad-b13b-e92982325848' User entered '14 Nov 2020 06:11:05' | System | 14 Nov 2020 12:11:07 |
| | System | 14 Nov 2020 12:11:07 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '14 Nov 2020 00:01' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 Mar 2021 22:48:55 |
| Data entry locked. | System | 10 Aug 2020 19:45:55 |
| User entered '18 Nov 2020 23:59' | System | 10 Aug 2020 19:45:55 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 103' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-21T14:44:29', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'a80cafa8-fc19-4677-9829-3ce7d871e530' | System | 21 Nov 2020 20:44:37 |
| User entered 'No (N)' | System | 21 Nov 2020 20:44:37 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-21T14:44:31', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'a80cafa8-fc19-4677-9829-3ce7d871e530' | System | 21 Nov 2020 20:44:37 |
| User entered 'No (N)' | System | 21 Nov 2020 20:44:37 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-21T14:44:35', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'a80cafa8-fc19-4677-9829-3ce7d871e530' User entered '21 Nov 2020 14:44:35' | System | 21 Nov 2020 20:44:37 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '18 Nov 2020 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '22 Nov 2020 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 110' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-25T05:39:28', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2c45bfb4-c376-4b08-8874-12e950744ef7' | System | 25 Nov 2020 11:39:37 |
| User entered 'No (N)' | System | 25 Nov 2020 11:39:37 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-25T05:39:31', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2c45bfb4-c376-4b08-8874-12e950744ef7' | System | 25 Nov 2020 11:39:37 |
| User entered 'No (N)' | System | 25 Nov 2020 11:39:37 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-11-25T05:39:34', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '2c45bfb4-c376-4b08-8874-12e950744ef7' User entered '25 Nov 2020 05:39:34' | System | 25 Nov 2020 11:39:37 |
| | System | 25 Nov 2020 11:39:37 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '25 Nov 2020 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '29 Nov 2020 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 117' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-02T05:30:33', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '42342965-1bd6-46c7-99a1-c0d796734cae' User entered 'No (N)' | System | 02 Dec 2020 11:30:45 |
| | System | 02 Dec 2020 11:30:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-02T05:30:35', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '42342965-1bd6-46c7-99a1-c0d796734cae' User entered 'No (N)' | System | 02 Dec 2020 11:30:45 |
| | System | 02 Dec 2020 11:30:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-02T05:30:42', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '42342965-1bd6-46c7-99a1-c0d796734cae' User entered '02 Dec 2020 05:30:42' | System | 02 Dec 2020 11:30:45 |
| | System | 02 Dec 2020 11:30:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '02 Dec 2020 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '06 Dec 2020 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 124' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-09T05:43:51', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'cad35733-79c8-4364-8318-563f07518d0b' | System | 09 Dec 2020 11:43:59 |
| User entered 'No (N)' | System | 09 Dec 2020 11:43:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-09T05:43:53', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'cad35733-79c8-4364-8318-563f07518d0b' | System | 09 Dec 2020 11:43:59 |
| User entered 'No (N)' | System | 09 Dec 2020 11:43:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-09T05:43:56', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'cad35733-79c8-4364-8318-563f07518d0b' User entered '09 Dec 2020 05:43:56' | System | 09 Dec 2020 11:43:59 |
| | System | 09 Dec 2020 11:43:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '09 Dec 2020 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '13 Dec 2020 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 131' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-16T05:36:47', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8dbfb046-c73a-45f1-9194-44c8d7d6cf19' | System | 16 Dec 2020 11:36:57 |
| User entered 'No (N)' | System | 16 Dec 2020 11:36:57 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-16T05:36:52', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8dbfb046-c73a-45f1-9194-44c8d7d6cf19' | System | 16 Dec 2020 11:36:57 |
| User entered 'No (N)' | System | 16 Dec 2020 11:36:57 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-16T05:36:54', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '8dbfb046-c73a-45f1-9194-44c8d7d6cf19' User entered '16 Dec 2020 05:36:54' | System | 16 Dec 2020 11:36:57 |
| | System | 16 Dec 2020 11:36:57 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '16 Dec 2020 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '20 Dec 2020 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 138' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-23T05:25:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'c2ba16d2-5d09-4be9-879c-c94748df6019' User entered 'No (N)' | System | 23 Dec 2020 11:25:08 |
| | System | 23 Dec 2020 11:25:08 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-23T05:25:03', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'c2ba16d2-5d09-4be9-879c-c94748df6019' User entered 'No (N)' | System | 23 Dec 2020 11:25:08 |
| | System | 23 Dec 2020 11:25:08 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-23T05:25:05', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'c2ba16d2-5d09-4be9-879c-c94748df6019' User entered '23 Dec 2020 05:25:05' | System | 23 Dec 2020 11:25:08 |
| | System | 23 Dec 2020 11:25:08 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '23 Dec 2020 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '27 Dec 2020 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 145' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-30T06:36:08', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '989c8435-e905-4b91-906c-1b4d6ed16f67' | System | 30 Dec 2020 12:36:14 |
| User entered 'No (N)' | System | 30 Dec 2020 12:36:14 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-30T06:36:10', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '989c8435-e905-4b91-906c-1b4d6ed16f67' | System | 30 Dec 2020 12:36:14 |
| User entered 'No (N)' | System | 30 Dec 2020 12:36:14 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2020-12-30T06:36:12', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '989c8435-e905-4b91-906c-1b4d6ed16f67' User entered '30 Dec 2020 06:36:12' | System | 30 Dec 2020 12:36:14 |
| | System | 30 Dec 2020 12:36:14 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '30 Dec 2020 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '03 Jan 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 152' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-06T05:46:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '087c19b6-cf41-42df-88cd-9d10f6d78f68' | System | 06 Jan 2021 11:46:09 |
| User entered 'No (N)' | System | 06 Jan 2021 11:46:09 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-06T05:46:02', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '087c19b6-cf41-42df-88cd-9d10f6d78f68' | System | 06 Jan 2021 11:46:09 |
| User entered 'No (N)' | System | 06 Jan 2021 11:46:09 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-06T05:46:05', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '087c19b6-cf41-42df-88cd-9d10f6d78f68' | System | 06 Jan 2021 11:46:09 |
| User entered '06 Jan 2021 05:46:05' | System | 06 Jan 2021 11:46:09 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '06 Jan 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '10 Jan 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 159' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-13T05:37:26', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'c30f71fa-d602-48f2-a564-555bec735ddc' | System | 13 Jan 2021 11:37:36 |
| User entered 'No (N)' | System | 13 Jan 2021 11:37:36 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-13T05:37:30', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'c30f71fa-d602-48f2-a564-555bec735ddc' | System | 13 Jan 2021 11:37:36 |
| User entered 'No (N)' | System | 13 Jan 2021 11:37:36 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-13T05:37:33', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'c30f71fa-d602-48f2-a564-555bec735ddc' User entered '13 Jan 2021 05:37:33' | System | 13 Jan 2021 11:37:36 |
| | System | 13 Jan 2021 11:37:36 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '13 Jan 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '17 Jan 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 166' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-20T05:45:38', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'a69483a4-f157-4278-9146-426aafae5aa2' | System | 20 Jan 2021 11:45:46 |
| User entered 'No (N)' | System | 20 Jan 2021 11:45:46 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-20T05:45:41', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'a69483a4-f157-4278-9146-426aafae5aa2' | System | 20 Jan 2021 11:45:46 |
| User entered 'No (N)' | System | 20 Jan 2021 11:45:46 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-20T05:45:44', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'a69483a4-f157-4278-9146-426aafae5aa2' User entered '20 Jan 2021 05:45:44' | System | 20 Jan 2021 11:45:46 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '20 Jan 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '24 Jan 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 173' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-27T05:33:33', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '60a45c88-7e33-4bf6-8b2c-34d83e6bc448' | System | 27 Jan 2021 11:33:45 |
| User entered 'No (N)' | System | 27 Jan 2021 11:33:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-27T05:33:38', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '60a45c88-7e33-4bf6-8b2c-34d83e6bc448' | System | 27 Jan 2021 11:33:45 |
| User entered 'No (N)' | System | 27 Jan 2021 11:33:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-01-27T05:33:40', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '60a45c88-7e33-4bf6-8b2c-34d83e6bc448' User entered '27 Jan 2021 05:33:40' | System | 27 Jan 2021 11:33:45 |
| | System | 27 Jan 2021 11:33:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '27 Jan 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '31 Jan 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 180' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-03T05:39:45', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '211db912-7238-4828-82b2-1af3bc98d2fc' User entered 'No (N)' | System | 03 Feb 2021 11:39:54 |
| | System | 03 Feb 2021 11:39:54 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-03T05:39:47', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '211db912-7238-4828-82b2-1af3bc98d2fc' | System | 03 Feb 2021 11:39:54 |
| User entered 'No (N)' | System | 03 Feb 2021 11:39:54 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-03T05:39:49', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '211db912-7238-4828-82b2-1af3bc98d2fc' User entered '03 Feb 2021 05:39:49' | System | 03 Feb 2021 11:39:54 |
| | System | 03 Feb 2021 11:39:54 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '03 Feb 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '07 Feb 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 187' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-10T05:52:56', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1e47fd80-b0a8-412d-b075-95a1e303d42a' User entered 'No (N)' | System | 10 Feb 2021 12:02:17 |
| | System | 10 Feb 2021 12:02:17 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-10T05:52:58', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1e47fd80-b0a8-412d-b075-95a1e303d42a' User entered 'No (N)' | System | 10 Feb 2021 12:02:17 |
| | System | 10 Feb 2021 12:02:17 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-10T05:53:01', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1e47fd80-b0a8-412d-b075-95a1e303d42a' User entered '10 Feb 2021 05:53:01' | System | 10 Feb 2021 12:02:17 |
| | System | 10 Feb 2021 12:02:17 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '10 Feb 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '14 Feb 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 194' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-17T05:30:46', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '275772ca-fc8b-4806-b005-96a81a171736' User entered 'No (N)' | System | 17 Feb 2021 11:30:59 |
| | System | 17 Feb 2021 11:30:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-17T05:30:54', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '275772ca-fc8b-4806-b005-96a81a171736' User entered 'No (N)' | System | 17 Feb 2021 11:30:59 |
| | System | 17 Feb 2021 11:30:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-17T05:30:56', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '275772ca-fc8b-4806-b005-96a81a171736' User entered '17 Feb 2021 05:30:56' | System | 17 Feb 2021 11:30:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '17 Feb 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '21 Feb 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 201' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-24T11:28:57', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e6795a82-a19b-4a3c-ab7d-1a678b2b0e8b' User entered 'No (N)' | System | 24 Feb 2021 16:29:08 |
| | System | 24 Feb 2021 16:29:08 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-24T11:28:59', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e6795a82-a19b-4a3c-ab7d-1a678b2b0e8b' User entered 'No (N)' | System | 24 Feb 2021 16:29:08 |
| | System | 24 Feb 2021 16:29:08 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-02-24T11:29:04', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e6795a82-a19b-4a3c-ab7d-1a678b2b0e8b' User entered '24 Feb 2021 11:29:04' | System | 24 Feb 2021 16:29:08 |
| | System | 24 Feb 2021 16:29:08 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '24 Feb 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '28 Feb 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 208' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-05T12:37:18-06:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'd677648e-3de9-4e5c-b4fe-a263b865edd0' | System | 05 Mar 2021 18:37:32 |
| User entered 'No (N)' | System | 05 Mar 2021 18:37:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-05T12:37:20-06:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'd677648e-3de9-4e5c-b4fe-a263b865edd0' | System | 05 Mar 2021 18:37:32 |
| User entered 'No (N)' | System | 05 Mar 2021 18:37:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-05T12:37:23-06:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'd677648e-3de9-4e5c-b4fe-a263b865edd0' | System | 05 Mar 2021 18:37:32 |
| User entered '05 Mar 2021 12:37:23' | System | 05 Mar 2021 18:37:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '03 Mar 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '07 Mar 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 215' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-12T11:31:22-06:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '0c681236-8cf9-4aac-9706-2f6f287ae920' | System | 12 Mar 2021 17:31:34 |
| User entered 'No (N)' | System | 12 Mar 2021 17:31:34 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-12T11:31:24-06:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '0c681236-8cf9-4aac-9706-2f6f287ae920' | System | 12 Mar 2021 17:31:34 |
| User entered 'No (N)' | System | 12 Mar 2021 17:31:34 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-12T11:31:27-06:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '0c681236-8cf9-4aac-9706-2f6f287ae920' User entered '12 Mar 2021 11:31:27' | System | 12 Mar 2021 17:31:34 |
| | System | 12 Mar 2021 17:31:34 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '10 Mar 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '14 Mar 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 222' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-19T12:00:21-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'ab628dec-f7a4-44f0-962d-eee0e95b7aa8' | System | 19 Mar 2021 17:00:45 |
| User entered 'No (N)' | System | 19 Mar 2021 17:00:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-19T12:00:24-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'ab628dec-f7a4-44f0-962d-eee0e95b7aa8' | System | 19 Mar 2021 17:00:45 |
| User entered 'No (N)' | System | 19 Mar 2021 17:00:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-19T12:00:26-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'ab628dec-f7a4-44f0-962d-eee0e95b7aa8' | System | 19 Mar 2021 17:00:45 |
| User entered '19 Mar 2021 12:00:26' | System | 19 Mar 2021 17:00:45 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '17 Mar 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '21 Mar 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 229' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-24T05:41:41-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '966fd5c6-e877-489e-a1c6-4e0f7295d39c' | System | 24 Mar 2021 10:41:49 |
| User entered 'No (N)' | System | 24 Mar 2021 10:41:49 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-24T05:41:43-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '966fd5c6-e877-489e-a1c6-4e0f7295d39c' | System | 24 Mar 2021 10:41:49 |
| User entered 'No (N)' | System | 24 Mar 2021 10:41:49 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-24T05:41:45-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '966fd5c6-e877-489e-a1c6-4e0f7295d39c' User entered '24 Mar 2021 05:41:45' | System | 24 Mar 2021 10:41:49 |
| | System | 24 Mar 2021 10:41:49 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '24 Mar 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '28 Mar 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 236' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-31T05:44:37-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aca5107e-d60d-48d2-9a4b-2a3f0f9d6368' | System | 31 Mar 2021 10:45:25 |
| User entered 'Yes (Y)' | System | 31 Mar 2021 10:45:25 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-31T05:44:41-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aca5107e-d60d-48d2-9a4b-2a3f0f9d6368' | System | 31 Mar 2021 10:45:25 |
| User entered 'No (N)' | System | 31 Mar 2021 10:45:25 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-31T05:44:46-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aca5107e-d60d-48d2-9a4b-2a3f0f9d6368' | System | 31 Mar 2021 10:45:25 |
| User entered 'No (N)' | System | 31 Mar 2021 10:45:25 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-31T05:45:01-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aca5107e-d60d-48d2-9a4b-2a3f0f9d6368' | System | 31 Mar 2021 10:45:25 |
| User entered 'Yes (Y)' | System | 31 Mar 2021 10:45:25 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-31T05:45:09-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aca5107e-d60d-48d2-9a4b-2a3f0f9d6368' | System | 31 Mar 2021 10:45:25 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 31 Mar 2021 10:45:25 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-31T05:45:12-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'aca5107e-d60d-48d2-9a4b-2a3f0f9d6368' User entered '31 Mar 2021 05:45:12' | System | 31 Mar 2021 10:45:25 |
| | System | 31 Mar 2021 10:45:25 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '31 Mar 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '04 Apr 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 243' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-07T05:40:50-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '6968c0bc-ac37-4cc3-a5f9-ae0eda8c1108' | System | 07 Apr 2021 10:40:59 |
| User entered 'No (N)' | System | 07 Apr 2021 10:40:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-07T05:40:53-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '6968c0bc-ac37-4cc3-a5f9-ae0eda8c1108' | System | 07 Apr 2021 10:40:59 |
| User entered 'No (N)' | System | 07 Apr 2021 10:40:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-07T05:40:56-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '6968c0bc-ac37-4cc3-a5f9-ae0eda8c1108' | System | 07 Apr 2021 10:40:59 |
| User entered '07 Apr 2021 05:40:56' | System | 07 Apr 2021 10:40:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '07 Apr 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '11 Apr 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 250' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-16T12:00:34-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e3d85911-4f2a-45e3-8e93-1e1090c9c7ce' | System | 16 Apr 2021 17:01:14 |
| User entered 'No (N)' | System | 16 Apr 2021 17:01:14 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-16T12:00:37-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e3d85911-4f2a-45e3-8e93-1e1090c9c7ce' | System | 16 Apr 2021 17:01:14 |
| User entered 'No (N)' | System | 16 Apr 2021 17:01:14 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-16T12:00:40-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: 'e3d85911-4f2a-45e3-8e93-1e1090c9c7ce' User entered '16 Apr 2021 12:00:40' | System | 16 Apr 2021 17:01:14 |
| | System | 16 Apr 2021 17:01:14 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '14 Apr 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '18 Apr 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 257' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-21T05:42:28-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '27766cb3-2a30-44a4-8987-10c6b09e8259' | System | 21 Apr 2021 10:42:59 |
| User entered 'Yes (Y)' | System | 21 Apr 2021 10:42:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-21T05:42:32-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '27766cb3-2a30-44a4-8987-10c6b09e8259' | System | 21 Apr 2021 10:42:59 |
| User entered 'No (N)' | System | 21 Apr 2021 10:42:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-21T05:42:36-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '27766cb3-2a30-44a4-8987-10c6b09e8259' | System | 21 Apr 2021 10:42:59 |
| User entered 'No (N)' | System | 21 Apr 2021 10:42:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-21T05:42:40-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '27766cb3-2a30-44a4-8987-10c6b09e8259' | System | 21 Apr 2021 10:42:59 |
| User entered 'Yes (Y)' | System | 21 Apr 2021 10:42:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-21T05:42:45-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '27766cb3-2a30-44a4-8987-10c6b09e8259' | System | 21 Apr 2021 10:42:59 |
| User entered 'I confirm I have read this message and will call the study clinic immediately (9)' | System | 21 Apr 2021 10:42:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-21T05:42:48-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '27766cb3-2a30-44a4-8987-10c6b09e8259' | System | 21 Apr 2021 10:42:59 |
| User entered '21 Apr 2021 05:42:48' | System | 21 Apr 2021 10:42:59 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '21 Apr 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '25 Apr 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 264' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-28T05:30:40-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1491363a-388d-433f-bd87-a82cfca97d1b' | System | 28 Apr 2021 21:38:35 |
| User entered 'No (N)' | System | 28 Apr 2021 21:38:35 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-28T05:30:44-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1491363a-388d-433f-bd87-a82cfca97d1b' | System | 28 Apr 2021 21:38:35 |
| User entered 'No (N)' | System | 28 Apr 2021 21:38:35 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Date and time of submission](#)

| Audit | User | Time (GMT) |
|--|--------|----------------------|
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-04-28T05:30:48-05:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '1491363a-388d-433f-bd87-a82cfca97d1b' | System | 28 Apr 2021 21:38:35 |
| User entered '28 Apr 2021 05:30:48' | System | 28 Apr 2021 21:38:35 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '28 Apr 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '02 May 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 271' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '05 May 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '09 May 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 278' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '12 May 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '16 May 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 285' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '19 May 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '23 May 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 292' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '26 May 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '30 May 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 299' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '02 Jun 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '06 Jun 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 306' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '09 Jun 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '13 Jun 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 313' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '16 Jun 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '20 Jun 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 320' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '23 Jun 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '27 Jun 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 327' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '30 Jun 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '04 Jul 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 334' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '07 Jul 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '11 Jul 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 341' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '14 Jul 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '18 Jul 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 348' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '21 Jul 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '25 Jul 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 355' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '28 Jul 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '01 Aug 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 362' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '04 Aug 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '08 Aug 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 369' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '11 Aug 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '15 Aug 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 376' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '18 Aug 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '22 Aug 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 383' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '25 Aug 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '29 Aug 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 390' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '01 Sep 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '05 Sep 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 397' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '08 Sep 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '12 Sep 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 404' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '15 Sep 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '19 Sep 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 411' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '22 Sep 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '26 Sep 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 418' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '29 Sep 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '03 Oct 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 425' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '06 Oct 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '10 Oct 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 432' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '13 Oct 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '17 Oct 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 439' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '20 Oct 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '24 Oct 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 446' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '27 Oct 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '31 Oct 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 453' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '03 Nov 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '07 Nov 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 460' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '10 Nov 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '14 Nov 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 467' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '17 Nov 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '21 Nov 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 474' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '24 Nov 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '28 Nov 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 481' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '01 Dec 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '05 Dec 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 488' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '08 Dec 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '12 Dec 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 495' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '15 Dec 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '19 Dec 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 502' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '22 Dec 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '26 Dec 2021 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 509' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '29 Dec 2021 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '02 Jan 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 516' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '05 Jan 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '09 Jan 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 523' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '12 Jan 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '16 Jan 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 530' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '19 Jan 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '23 Jan 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 537' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '26 Jan 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '30 Jan 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 544' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '02 Feb 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '06 Feb 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 551' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '09 Feb 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '13 Feb 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 558' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '16 Feb 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '20 Feb 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 565' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '23 Feb 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '27 Feb 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 572' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '02 Mar 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '06 Mar 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 579' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '09 Mar 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '13 Mar 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 586' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '16 Mar 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '20 Mar 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 593' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '23 Mar 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '27 Mar 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 600' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '30 Mar 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '03 Apr 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 607' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '06 Apr 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '10 Apr 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 614' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '13 Apr 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '17 Apr 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 621' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '20 Apr 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '24 Apr 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 628' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '27 Apr 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '01 May 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 635' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '04 May 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '08 May 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 642' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '11 May 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '15 May 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 649' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '18 May 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '22 May 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 656' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '25 May 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '29 May 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 663' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '01 Jun 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '05 Jun 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 670' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '08 Jun 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '12 Jun 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 677' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '15 Jun 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '19 Jun 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 684' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '22 Jun 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '26 Jun 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 691' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '29 Jun 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '03 Jul 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 698' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '06 Jul 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '10 Jul 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 705' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '13 Jul 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '17 Jul 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 712' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '20 Jul 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '24 Jul 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 719' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '27 Jul 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '31 Jul 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 726' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '03 Aug 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '07 Aug 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 733' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '10 Aug 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '14 Aug 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 740' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '17 Aug 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '21 Aug 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 747' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '24 Aug 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '28 Aug 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 754' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '31 Aug 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '04 Sep 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 761' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '07 Sep 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '11 Sep 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 768' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '14 Sep 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '18 Sep 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 775' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '21 Sep 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '25 Sep 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 782' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '28 Sep 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '02 Oct 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 789' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '05 Oct 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '09 Oct 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

TIMEPOINT

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered 'Day 796' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Open Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '12 Oct 2022 00:01' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 21:58:57

[Patient Cloud Close Date & Time](#)

| Audit | User | Time (GMT) |
|---|--------|----------------------|
| Amendment Manager: Data entry locked. | System | 19 Nov 2020 02:55:32 |
| Amendment Manager: User entered '16 Oct 2022 23:59' | System | 19 Nov 2020 02:55:32 |

US3032171

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:58:57

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:18:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-05T12:37:05-06:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '32402bbe-9c5b-46fa-9e0c-9b7d50fc153c' | System | 05 Mar 2021 18:37:12 |
| User entered 'No (N)' | System | 05 Mar 2021 18:37:12 |

US3032171

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 21:58:57

[Date & Time of Submission](#)

| Audit | User | Time (GMT) |
|--|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 24 Apr 2021 12:18:47 |
| External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (B5072BB8-F367-46FC-A236-9CC9718362CC)', Time: '2021-03-05T12:37:09-06:00', User OID: 'PatientReportedOutcome (US3032171)', ODM File OID: '32402bbe-9c5b-46fa-9e0c-9b7d50fc153c' User entered '05 Mar 2021 12:37:09' | System | 05 Mar 2021 18:37:12 |
| | System | 05 Mar 2021 18:37:12 |

US3032171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Dec 2020 19:47:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 20:05:00 |
| User entered 'Yes (Y)' | Linden DeBoer (b) (4) (b) (4) | 01 Dec 2020 15:28:59 |

US3032171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Dec 2020 19:47:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 20:05:00 |
| User entered '13 Nov 2020' | Linden DeBoer (b) (4) (b) (4) | 01 Dec 2020 15:28:59 |

US3032171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Dec 2020 19:47:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 20:05:00 |
| User entered 'Contact Made (CONTACT MADE)' | Linden DeBoer (b) (4) (b) (4) | 01 Dec 2020 15:28:59 |

US3032171

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Dec 2020 19:47:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 20:05:00 |
| User entered empty. | Linden DeBoer (b) (4) (b) (4) | 01 Dec 2020 15:28:59 |

US3032171

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Dec 2020 19:47:51 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 20:05:20 |
| User entered 'Yes (Y)' | Linden DeBoer (b) (4) (b) (4) | 01 Dec 2020 15:29:04 |

US3032171

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 00:01:57 |
| User entered 'I' | System | 01 Dec 2020 15:29:04 |

US3032171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:09:39 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Dec 2020 15:53:54 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 17 Dec 2020 14:37:56 |

US3032171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:09:39 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Dec 2020 15:53:54 |
| User entered '16 Dec 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 17 Dec 2020 14:37:56 |

US3032171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:09:39 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Dec 2020 15:53:54 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 17 Dec 2020 14:37:56 |

US3032171

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:09:39 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Dec 2020 15:53:54 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 17 Dec 2020 14:37:56 |

US3032171

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:09:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Dec 2020 15:53:54 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 17 Dec 2020 14:38:09 |

US3032171

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| User entered 'I' | System | 17 Dec 2020 14:38:09 |

US3032171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:10:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Mar 2021 23:05:01 |
| | (b) (4) | |

US3032171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Apr 2021 18:22:00 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 20 Apr 2021 17:59:41 |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Samantha Wieseler (b) (4) | 20 Apr 2021 17:27:35 |
| DataPoint Un-verified. | (b) (4) Samantha Wieseler (b) (4) | 20 Apr 2021 17:20:55 |
| Signature has been broken. | (b) (4) Samantha Wieseler (b) (4) | 20 Apr 2021 17:20:55 |
| User entered '15 Feb 2021' reason for change: Data Entry Error | (b) (4) Samantha Wieseler (b) (4) | 20 Apr 2021 17:20:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 14 Apr 2021 19:21:28 |
| User closed query 'Per the source this call was conducted 21JAN21 please update' (Site from CRA). | (b) (4) (u) (4), (b) (6) | 13 Apr 2021 15:30:17 |
| DataPoint Verified. | | 13 Apr 2021 15:30:14 |
| Query 'Per the source this call was conducted 21JAN21 please update' answered with 'updated' (Site from CRA). | Samantha Wieseler (b) (4) | 06 Apr 2021 20:00:16 |
| Signature has been broken. | (b) (4) Samantha Wieseler (b) (4) | 06 Apr 2021 19:59:57 |
| User entered '21 Jan 2021' reason for change: Data Entry Error | Samantha Wieseler (b) (4) | 06 Apr 2021 19:59:57 |
| User opened query 'Per the source this call was conducted 21JAN21 please update' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:10:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered '18 Jan 2021' | (b) (4) Samantha Wieseler (b) (4) | 08 Mar 2021 23:05:01 |

US3032171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:10:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Samantha Wieseler (b) (4) (b) (4) | 08 Mar 2021 23:05:01 |

US3032171

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:10:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered empty. | (b) (4) Samantha Wieseler (b) (4) (b) (4) | 08 Mar 2021 23:05:01 |

US3032171

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 02 Apr 2021 19:11:04 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Mar 2021 23:05:05 |
| | (b) (4) | |

US3032171

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| User entered 'I' | System | 08 Mar 2021 23:05:05 |

US3032171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 13 Apr 2021 15:31:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Yes (Y)' | (b) (4) Samantha Wieseler (b) (4) (b) (4) | 08 Mar 2021 23:08:06 |

US3032171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| User closed query 'Source for the safety call cannot be located' (Site from CRA). | | 13 Apr 2021 15:31:08 |
| DataPoint Verified. | | 13 Apr 2021 15:31:05 |
| Query 'Source for the safety call cannot be located' answered with 'source has been located' (Site from CRA). | Samantha Wieseler (b) (4) | 06 Apr 2021 20:05:14 |
| User opened query 'Source for the safety call cannot be located' (Site from CRA). | (b) (4), (b) (6) | 02 Apr 2021 19:14:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered '15 Feb 2021' | Samantha Wieseler (b) (4) | 08 Mar 2021 23:08:06 |

US3032171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 13 Apr 2021 15:31:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Samantha Wieseler (b) (4) (b) (4) | 08 Mar 2021 23:08:06 |

US3032171

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 13 Apr 2021 15:31:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered empty. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Mar 2021 23:08:06 |
| | (b) (4) | |

US3032171

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| DataPoint Verified. | | 13 Apr 2021 15:31:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Mar 2021 23:08:09 |
| | (b) (4) | |

US3032171

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 06:49:42 |
| User entered 'I' | System | 08 Mar 2021 23:08:09 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:27 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:25:06 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:27 |
| User entered '19 Mar 2021' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:25:06 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:27 |
| User entered 'Clinic (Clinic)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:25:06 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User entered 'VISIT4' | System | 19 Mar 2021 16:25:06 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Were vital signs assessed?

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM). | | 01 Apr 2021 01:46:52 |
| Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'Per protocol, Vital signs not needed on visit 4' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 30 Mar 2021 15:13:47 |
| User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however vital signs on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 30 Mar 2021 06:39:09 |
| User entered 'No (N)' | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User entered empty. | System | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User entered empty. | System | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User entered empty. | System | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User entered empty. | System | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:32 |
| User entered empty. | Samantha Wieseler (b) (4) (b) (4) | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User entered empty. | System | 29 Mar 2021 15:29:55 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| | | |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| | | |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:37 |
| User entered 'No (N)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:27:13 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:37 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:27:13 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User closed query 'Per CDM Re-query: Per response visit 4 was drawn, however for "Was the sample collected?" is reported as " No" here, kindly review and amend as appropriate. ' (Site from DM). DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 20:53:00 |
| | | 02 Apr 2021 19:16:56 |
| Query 'Per CDM Re-query: Per response visit 4 was drawn, however for "Was the sample collected?" is reported as " No" here, kindly review and amend as appropriate. ' answered with 'Lab was drawn as part of OL-3 Source using corresponding kit ' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 01 Apr 2021 16:58:36 |
| User opened query 'Per CDM Re-query: Per response visit 4 was drawn, however for "Was the sample collected?" is reported as " No" here, kindly review and amend as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 01 Apr 2021 01:55:47 |
| User closed query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM). | | 01 Apr 2021 01:55:47 |
| Query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' answered with 'visit 4 was collected not OL3' (Site from DM). | Samantha Wieseler (b) (4) (b) (4) | 30 Mar 2021 18:52:31 |
| User opened query 'Per CDM: Visit 4 Day 209 and OL-D57 were performed on same day, however immunogenicity assessment performed on Visit 4 Day 209 is No and on OL D-57 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 30 Mar 2021 06:39:28 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|-----------------------|----------------------------------|----------------------|
| User entered 'No (N)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:27:28 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:56 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:27:28 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:16:56 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:27:28 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User entered empty. | System | 19 Mar 2021 16:27:28 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:17:02 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:27:32 |

US3032171

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 27 Apr 2021 10:50:20 |
| User entered 'I' | System | 19 Mar 2021 16:27:32 |

US3032171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Apr 2021 18:22:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 15:22:05 |

US3032171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Apr 2021 18:22:00 |
| User entered '19 Apr 2021' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 15:22:05 |

US3032171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Apr 2021 18:22:00 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 15:22:05 |

US3032171

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Apr 2021 18:22:00 |
| User entered empty. | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 15:22:05 |

US3032171

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Apr 2021 18:22:00 |
| User entered 'Yes (Y)' | (b) (4) (b) (4), (b) (6) | 22 Apr 2021 15:22:13 |

US3032171

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 22 Apr 2021 15:22:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:57

[Date of Contact](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:24 |
| User closed query 'Per GCL Lab Reconciliation Requery2: Saliva: Data needs to be recorded on the Saliva collection form of EDC as a 30Oct2020 sample is present in Preclarus. Please review Preclarus and if collected for the subject then update the data on the SALIVA Collection form of appropriate visit.' (Site from DM). | | 25 Jan 2021 07:01:18 |
| Query 'Per GCL Lab Reconciliation Requery2: Saliva: Data needs to be recorded on the Saliva collection form of EDC as a 30Oct2020 sample is present in Preclarus. Please review Preclarus and if collected for the subject then update the data on the SALIVA Collection form of appropriate visit.' answered with 'will update accordingly' (Site from DM). | Samantha Wieseler (b) (4) (b) (4) | 22 Jan 2021 21:13:00 |
| User opened query 'Per GCL Lab Reconciliation Requery2: Saliva: Data needs to be recorded on the Saliva collection form of EDC as a 30Oct2020 sample is present in Preclarus. Please review Preclarus and if collected for the subject then update the data on the SALIVA Collection form of appropriate visit.' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 10:18:03 |
| User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Per response " will update accordingly". Sample dated 30OCT2020 is not recorded in EDC. Please review Preclarus and update the EDC or clarify.' (Site from DM). | (b) (4), (b) (6) | 22 Jan 2021 10:18:03 |
| Query 'Per GCL Lab Reconciliation Requery: Saliva: Per response " will update accordingly". Sample dated 30OCT2020 is not recorded in EDC. Please review Preclarus and update the EDC or clarify.' answered with 'will update when more information is available.' (Site from DM). | Samantha Wieseler (b) (4) (b) (4) | 21 Jan 2021 22:27:24 |
| User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Per response " will update accordingly". Sample dated 30OCT2020 is not recorded in EDC. Please review Preclarus and update the EDC or clarify.' (Site from DM). | (b) (4), (b) (6) | 21 Jan 2021 05:08:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:57

[Date of Contact](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 21 Jan 2021 05:08:54 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' answered with 'will update accordingly' (Site from DM). | Samantha Wieseler (b) (4) | 19 Jan 2021 23:30:36 |
| User closed query 'Please reconcile and enter severity page' (Site from CRA). | (b) (4), (b) (6) | 29 Dec 2020 02:13:34 |
| Query 'Please reconcile and enter severity page' answered with 'this was completed on 24./Nov/2020' (Site from CRA). | Linden DeBoer (b) (4) | 03 Dec 2020 17:31:45 |
| User opened query 'Please reconcile and enter severity page' (Site from CRA). | (b) (4), (b) (6) | 22 Nov 2020 00:43:39 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness Visits in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected then update the details in Saliva collection log under appropriate visit. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 10:18:20 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:01 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '08 Sep 2020' | Linden DeBoer (b) (4) | 08 Sep 2020 16:44:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:57

[Time of Contact](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:24 |
| DataPoint Verified. | | 09 Nov 2020 17:22:01 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '10:00' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:44:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:57

[Date and Time of Contact \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:24 |
| User entered '08 Sep 2020 10:00' | System | 08 Sep 2020 16:44:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:57

[Type of Contact](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:24 |
| DataPoint Verified. | | 09 Nov 2020 17:22:01 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)' reason for change: Data Entry Error | (b) (4) | |
| | Linden DeBoer (b) (4) | 08 Sep 2020 16:44:13 |
| | (b) (4) | |
| User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)' | Linden DeBoer (b) (4) | 08 Sep 2020 16:44:05 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID-19 Contact

Generated On: 11 Aug 2021 21:58:57

[Has the subject reported symptoms of SARS-COV-2?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:24 |
| DataPoint Verified. | | 09 Nov 2020 17:22:01 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:44:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Day 1 (Day 1)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User closed query 'Per CDM: it appears that initial symptom date and Contact Date are the same: 08SEP2020. Please reconcile or clarify' (Site from DM). | (b) (4) (b) (4), (b) (6) | 12 Nov 2020 12:23:43 |
| Query 'Per CDM: it appears that initial symptom date and Contact Date are the same: 08SEP2020. Please reconcile or clarify' answered with 'data updated' (Site from DM). | Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 15:55:38 |
| DataPoint Un-verified. | Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 15:55:33 |
| Signature has been broken. | Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 15:55:33 |
| User entered '05 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 15:55:33 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User opened query 'Per CDM: it appears that initial symptom date and Contact Date are the same: 08SEP2020. Please reconcile or clarify' (Site from DM). | | 07 Nov 2020 12:42:49 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '08 Sep 2020' | Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:33 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:33 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:33 |
| change Data Entry Error | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '100' | Linden DeBoer (b) (4) | 08 Sep 2020 16:45:35 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:33 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:33 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:33 |
| change Data Entry Error | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '37.0' C | Linden DeBoer (b) (4) | 08 Sep 2020 16:45:35 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:36 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:40 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:45 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (1)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:45:35 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 2 (Day 2)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:35 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| | (b) (4) | |
| User entered '06 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '09 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 19:21:58 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| change Data Entry Error | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '99' | Linden DeBoer (b) (4) | 07 Oct 2020 19:21:58 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for | Linden DeBoer (b) (4) | 11 Nov 2020 15:55:57 |
| change Data Entry Error | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.3' F | Linden DeBoer (b) (4) | 07 Oct 2020 19:21:58 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (2)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:21:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 3 (Day 3)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:02:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| | (b) (4) | |
| User entered '07 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '10 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 19:45:00 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:02:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '100' | Linden DeBoer (b) (4) | 07 Oct 2020 19:45:00 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:02:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| | (b) (4) | |
| User entered missing code ND - Not Done; reason for change Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:56:14 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.6' F | Linden DeBoer (b) (4) | 07 Oct 2020 19:45:00 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (3)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:45:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 4 (Day 4)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:03:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered '08 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '11 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '100' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:03:02 |
| User signature succeeded. | | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| Signature has been broken. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered '37.0' C reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.3' F | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:03:04 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:03:54 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:04:02 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'Mild (Mild)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:04:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

Body Aches

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:04:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:04:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:47:01 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (4)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:04:24 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:57:52 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:47:01 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 5 (Day 5)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:05:01 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| | (b) (4) | |
| User entered '09 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '12 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 19:50:13 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:04:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| | (b) (4) | |
| User entered '98.3' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.0' F | Linden DeBoer (b) (4) | 07 Oct 2020 19:50:13 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:05:17 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:58:46 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:50:13 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (5)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:50:13 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 6 (Day 6)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:05:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| | (b) (4) | |
| User entered '10 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '13 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 19:51:46 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:05:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| | (b) (4) | |
| User entered '100' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '99' | Linden DeBoer (b) (4) | 07 Oct 2020 19:51:46 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:05:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| | (b) (4) | |
| User entered '98.6' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 15:59:31 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.5' F | Linden DeBoer (b) (4) | 07 Oct 2020 19:51:46 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Moderate (Moderate)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (6)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:51:46 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 7 (Day 7)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:06:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| User entered '11 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '14 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 19:59:02 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:06:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| User entered '100' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '99' | Linden DeBoer (b) (4) | 07 Oct 2020 19:59:02 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:06:52 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| User entered '98.3' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.7' F | Linden DeBoer (b) (4) | 07 Oct 2020 19:59:02 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:06:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'Mild (Mild)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:59:02 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:00:15 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 19:59:02 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (7)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 19:59:02 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 8 (Day 8)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| User entered '12 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '15 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 20:00:57 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:07:21 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| User entered '98.0' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.2' F | Linden DeBoer (b) (4) | 07 Oct 2020 20:00:57 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:07:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'Mild (Mild)' | Linden DeBoer (b) (4) | 07 Oct 2020 20:00:57 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:07:40 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 20:00:57 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 24 Nov 2020 20:07:52 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:01:14 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 20:00:57 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (8)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:00:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 9 (Day 9)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| User entered '13 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '16 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 20:02:34 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| User entered '98.5' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '97.6' F | Linden DeBoer (b) (4) | 07 Oct 2020 20:02:34 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| User entered 'Moderate (Moderate)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'Mild (Mild)' | Linden DeBoer (b) (4) | 07 Oct 2020 20:02:34 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 20:02:34 |
| | (b) (4) | |

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Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 20:02:34 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (9)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:02:34 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 10 (Day 10)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| User entered '14 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '17 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 20:04:11 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| User entered '98.7' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.2' F | Linden DeBoer (b) (4) | 07 Oct 2020 20:04:11 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| User entered 'Mild (Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:02:52 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'None (None)' | Linden DeBoer (b) (4) | 07 Oct 2020 20:04:11 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (10)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:04:11 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 11 (Day 11)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:04:41 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:04:41 |
| | (b) (4) | |
| User entered '15 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:04:41 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '18 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 20:06:00 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:04:41 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:04:41 |
| | (b) (4) | |
| User entered '98.2' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:04:41 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.4' F | Linden DeBoer (b) (4) | 07 Oct 2020 20:06:00 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

Diarrhea

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (11)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:06:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 12 (Day 12)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:22 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:22 |
| | (b) (4) | |
| User entered '16 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '19 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 20:07:05 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:22 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:22 |
| | (b) (4) | |
| User entered '97.6' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:22 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.0' F | Linden DeBoer (b) (4) | 07 Oct 2020 20:07:05 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (12)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:07:05 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Day 13 (Day 13)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:49 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:49 |
| | (b) (4) | |
| User entered '17 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:49 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '20 Sep 2020' | Linden DeBoer (b) (4) | 07 Oct 2020 20:09:50 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:49 |
| | (b) (4) | |
| Signature has been broken. | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:49 |
| | (b) (4) | |
| User entered '98.2' F reason for change: Data Entry Error | Linden DeBoer (b) (4) | 11 Nov 2020 16:05:49 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:22:51 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '98.1' F | Linden DeBoer (b) (4) | 07 Oct 2020 20:09:50 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (13)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 09 Nov 2020 17:22:51 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 07 Oct 2020 20:09:50 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Day 14 (Day 14)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '18 Sep 2020' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '98.4' F | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (14)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:06:54 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Day 15 (Day 15)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Apr 2021 19:18:13 |
| User closed query 'Please confirm if Day 15 is 19SEP as Day 16 is listed for the same date' (Site from CRA). | | 02 Apr 2021 19:18:11 |
| Query 'Please confirm if Day 15 is 19SEP as Day 16 is listed for the same date' answered with 'updated' (Site from CRA). | Samantha Wieseler (b) (4) | 19 Jan 2021 23:39:53 |
| DataPoint Un-verified. | (b) (4) | |
| | (b) (4), (b) (6) | 19 Jan 2021 23:39:28 |
| User opened query 'Please confirm if Day 15 is 19SEP as Day 16 is listed for the same date' (Site from CRA). | | 19 Jan 2021 23:38:01 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '19 Sep 2020' | (b) (4) | |
| | Linden DeBoer (b) (4) | 11 Nov 2020 16:07:57 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '98.0' F | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Muscle Aches \(Myalgia\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (15)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:07:57 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User closed query 'Per CDM: Day 16 and Day 17 are recorded with duplicate dates. Please review and update the dates to resolve the duplicate entries and update the rest of the symptom log as necessary so that the days and dates are in the expected order.' (Site from DM). | | 26 Apr 2021 00:49:30 |
| Query 'Per CDM: Day 16 and Day 17 are recorded with duplicate dates. Please review and update the dates to resolve the duplicate entries and update the rest of the symptom log as necessary so that the days and dates are in the expected order.' answered with 'updated' (Site from DM). | Samantha Wieseler (b) (4) | 23 Apr 2021 12:54:02 |
| User opened query 'Per CDM: Day 16 and Day 17 are recorded with duplicate dates. Please review and update the dates to resolve the duplicate entries and update the rest of the symptom log as necessary so that the days and dates are in the expected order.' (Site from DM). | (b) (4), (b) (6) | 23 Apr 2021 05:33:45 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Day 16 (Day 16)' | Linden DeBoer (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User closed query 'Please confirm if day 16 is the correct date as Day 15 is listed as 19SEP.' (Site from CRA). | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:18:31 |
| DataPoint Verified. | | 02 Apr 2021 19:18:29 |
| Query 'Please confirm if day 16 is the correct date as Day 15 is listed as 19SEP.' answered with 'updated' (Site from CRA). | Samantha Wieseler (b) (4) (b) (4) | 19 Jan 2021 23:40:10 |
| Signature has been broken. | Samantha Wieseler (b) (4) (b) (4) | 19 Jan 2021 23:40:04 |
| User entered '20 Sep 2020' reason for change: Data Entry Error | Samantha Wieseler (b) (4) (b) (4) | 19 Jan 2021 23:40:04 |
| User opened query 'Please confirm if day 16 is the correct date as Day 15 is listed as 19SEP.' (Site from CRA). | (b) (4), (b) (6) | 19 Jan 2021 23:39:19 |
| DataPoint Un-verified. | | 19 Jan 2021 23:38:10 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '19 Sep 2020' | Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '98.0' F | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Runny Nose \(Rhinorrhea\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Vomiting](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (16)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:17:58 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Symptom Day](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Day 17 (Day 17)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Date](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| DataPoint Un-verified. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 23 Apr 2021 12:54:30 |
| Signature has been broken. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 23 Apr 2021 12:54:30 |
| | (b) (4) | |
| User entered '21 Sep 2020' reason for change: Data Entry Error | Samantha Wieseler (b) (4) | 23 Apr 2021 12:54:30 |
| | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:08:44 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| | (b) (4) | |
| User entered '20 Sep 2020' | Linden DeBoer (b) (4) | 11 Nov 2020 16:18:45 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Assessment Not Done](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 17:11:09 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '0' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:22 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '99' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[O2 Saturation Units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| User entered '%' | System | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Temperature](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:24 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '98.1' F | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Chills](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:25 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Cough](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:28 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Mild (Mild)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Shortness of Breath](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:31 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Difficulty Breathing](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:32 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Fatigue](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:34 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

Muscle Aches (Myalgia)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:35 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Body Aches](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:38 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Headache](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:41 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Taste](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:43 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[New Loss of Smell](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:45 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Nasal Congestion](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:57:03 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

Runny Nose (Rhinorrhea)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:51 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Nausea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:53 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

Vomiting

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:55 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Diarrhea](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:56 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Symptom Log (17)

Generated On: 11 Aug 2021 21:58:57

[Sore Throat](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 04 May 2021 04:32:29 |
| DataPoint Verified. | | 03 May 2021 23:44:42 |
| Data hard unlocked. | | 03 May 2021 19:25:59 |
| Data hard locked. | | 30 Apr 2021 12:19:14 |
| Data hard unlocked. | | 30 Apr 2021 04:46:19 |
| Data hard locked. | | 28 Apr 2021 22:39:30 |
| DataPoint Un-verified. | | 28 Apr 2021 21:56:57 |
| DataPoint Verified. | | 02 Dec 2020 20:08:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'None (None)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 11 Nov 2020 16:18:45 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[Date of Visit](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| User closed query 'Per GCL Lab Recon: it appears there si a SARS-CoV-2 sample with date of 08SEP2020 yet Illness Visit has not been completed. Please complete.' (Site from DM). | | 13 Nov 2020 06:55:17 |
| Query 'Per GCL Lab Recon: it appears there si a SARS-CoV-2 sample with date of 08SEP2020 yet Illness Visit has not been completed. Please complete.' answered with 'illness visit completed in EDC | Kelsey Kelley (b) (4) | 11 Nov 2020 17:51:55 |
| ' (Site from DM). | (b) (4) | |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:31:32 |
| User opened query 'Per GCL Lab Recon: it appears there si a SARS-CoV-2 sample with date of 08SEP2020 yet Illness Visit has not been completed. Please complete.' (Site from DM). | | 23 Oct 2020 08:32:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '08 Sep 2020' | Linden DeBoer (b) (4) | 08 Sep 2020 16:46:00 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| DataPoint Verified. | | 09 Nov 2020 17:31:32 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:46:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| User signature succeeded. | | 24 Nov 2020 20:28:34 |
| User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). DataPoint Verified. | | 23 Nov 2020 09:21:58 |
| | (b) (4), (b) (6) | 22 Nov 2020 00:43:46 |
| User closed query 'Please reconcile as positive result received from central lab' (Site from CRA). | | 22 Nov 2020 00:43:44 |
| Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'IS ON AE FORM' (Site from System). | Russell Herstein (b) (4) (b) (4) | 20 Nov 2020 22:56:30 |
| Query 'Please reconcile as positive results received from central lab' answered with 'DATA UPDATED' (Site from CRA). | Russell Herstein (b) (4) (b) (4) | 20 Nov 2020 22:56:21 |
| User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System). DataPoint Un-verified. | System | 20 Nov 2020 22:56:06 |
| | Russell Herstein (b) (4) (b) (4) | 20 Nov 2020 22:56:06 |
| Signature has been broken. | Russell Herstein (b) (4) (b) (4) | 20 Nov 2020 22:56:06 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Russell Herstein (b) (4) (b) (4) | 20 Nov 2020 22:56:06 |
| User opened query 'Please reconcile as positive results received from central lab' (Site from CRA). DataPoint Verified. | (b) (4), (b) (6) | 19 Nov 2020 05:18:06 |
| | | 09 Nov 2020 17:31:32 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:46:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[Date of Test](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| DataPoint Verified. | | 09 Nov 2020 17:31:32 |
| User closed query 'Per PCR Recon: It appears there are 2 different dates recorded for PCR Swab as Day 29: 08SEP2020 and 23SEP2020. Please review and make all updates accordingly or clarify.' (Site from DM). | | 23 Oct 2020 08:30:29 |
| Query 'Per PCR Recon: It appears there are 2 different dates recorded for PCR Swab as Day 29: 08SEP2020 and 23SEP2020. Please review and make all updates accordingly or clarify.' answered with '08SEP2020 this swab was done on this date' (Site from DM). | Linden DeBoer (b) (4) (b) (4) | 14 Oct 2020 12:28:57 |
| User opened query 'Per PCR Recon: It appears there are 2 different dates recorded for PCR Swab as Day 29: 08SEP2020 and 23SEP2020. Please review and make all updates accordingly or clarify.' (Site from DM). | (b) (4), (b) (6) | 14 Oct 2020 04:11:27 |
| Query 'Per CDM: It appears there are 2 different dates recorded PCR Swab as Day 29: 08SEP2020 and 21SEP2020. Please review and make all updates accordingly or clarify.' canceled (Site from DM). | | 14 Oct 2020 04:11:08 |
| User opened query 'Per CDM: It appears there are 2 different dates recorded PCR Swab as Day 29: 08SEP2020 and 21SEP2020. Please review and make all updates accordingly or clarify.' (Site from DM). | | 14 Oct 2020 04:08:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '08 Sep 2020' | Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:46:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[Type of Test Performed](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| DataPoint Verified. | | 09 Nov 2020 17:31:32 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' | (b) (4) Linden DeBoer (b) (4) | 08 Sep 2020 16:46:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| DataPoint Verified. | | 09 Nov 2020 17:31:32 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:46:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| DataPoint Verified. | | 09 Nov 2020 17:31:32 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 08 Sep 2020 16:46:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[Lab/ Institution Test Performed](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| DataPoint Verified. | | 09 Nov 2020 17:31:32 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) | |
| | Linden DeBoer (b) (4) | 08 Sep 2020 16:46:00 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

[CLIA Certified?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| DataPoint Verified. | | 09 Nov 2020 17:31:32 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) | |
| | Linden DeBoer (b) (4) | 08 Sep 2020 16:46:00 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: COVID Diagnostic Test

Generated On: 11 Aug 2021 21:58:57

COVID-19 Positive (CSA Programming Field Only)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:36 |
| User entered '1' | System | 20 Nov 2020 22:56:06 |
| User entered '0' | System | 08 Sep 2020 16:46:00 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

Did the subject have Respiratory Rates ≥ 30 per Minute?

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

Did the subject have Heart Rate \geq 125 beats per minute

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) | |
| | Russell Herstein (b) (4) | 24 Nov 2020 16:55:03 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Heart Rate](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

Did the subject have Oxygen Saturation of SpO2 \leq 93% on room air at sea level?

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Oxygen Saturation](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

Did the subject have PaO2/FIO2 Ratio < 300 mm Hg?

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) | |
| | Russell Herstein (b) (4) | 24 Nov 2020 16:55:03 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[PaO2](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

Did the subject have Respiratory failure?

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

Did the subject have Acute Respiratory Distress Syndrome (ARDS)?

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[High-Flow Oxygen?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Non-Invasive Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) | |
| | Russell Herstein (b) (4) | 24 Nov 2020 16:55:03 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Mechanical Ventilation?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) | |
| | Russell Herstein (b) (4) | 24 Nov 2020 16:55:03 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

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[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[ECMO?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

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[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
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| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) | |
| | Russell Herstein (b) (4) | 24 Nov 2020 16:55:03 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

Systolic Blood Pressure < 90 mmHg, Diastolic Blood Pressure < 60 mmHg

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Evidence of Shock Requires](#)

[Vasopressors](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) | |
| | Russell Herstein (b) (4) | 24 Nov 2020 16:55:03 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) | |
| | Russell Herstein (b) (4) | 24 Nov 2020 16:55:03 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Acute Renal Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Hepatic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) | |
| | Russell Herstein (b) (4) | 24 Nov 2020 16:55:03 |
| | (b) (4) | |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Neurologic Dysfunction?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Clinical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Radiographical Evidence](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Date of Assessment](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Admission to an intensive care unit due to SARS-CoV-2](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered 'No (N)' | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[Start Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Covid-19 Severity Assessment

Generated On: 11 Aug 2021 21:58:57

[End Date](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:42 |
| DataPoint Verified. | | 02 Dec 2020 20:10:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 24 Nov 2020 20:28:34 |
| User entered empty. | (b) (4) Russell Herstein (b) (4) (b) (4) | 24 Nov 2020 16:55:03 |

US3032171

Folder: Covid-19 Assessment 08 Sep 2020

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 21:58:57

[Generate Next COVID-19 Assessment](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 28 Apr 2021 22:39:47 |
| DataPoint Verified. | | 02 Apr 2021 19:19:17 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Dec 2020 19:47:17 |
| DataPoint Un-verified. | (b) (4) | |
| | Linden DeBoer (b) (4) | 03 Dec 2020 17:23:51 |
| Signature has been broken. | (b) (4) | |
| | Linden DeBoer (b) (4) | 03 Dec 2020 17:23:51 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) | |
| | Linden DeBoer (b) (4) | 03 Dec 2020 17:23:51 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:31:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Linden DeBoer (b) (4) | 08 Sep 2020 16:46:06 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession #1F619058914 is reported with 14sep2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Feb 2021 12:00:05 |
| Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession #1F619058914 is reported with 14sep2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'sample was collected on Day 3 being the 10th of Sep 2020' (Site from DM). | Samantha Wieseler (b) (4) | 10 Feb 2021 14:14:53 |
| User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 3 sample with Accession #1F619058914 is reported with 14sep2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 05 Feb 2021 15:52:15 |
| User accepted default value 'Day 3 (Day 3)' | Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 16 Dec 2020 20:09:11 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10,12SEP2020 and 05OCT2020 is recorded under Illness Visit Day 3,5,28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 14 Dec 2020 04:43:14 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10,12SEP2020 and 05OCT2020 is recorded under Illness Visit Day 3,5,28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'sample was shipped' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 11 Dec 2020 15:26:29 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10,12SEP2020 and 05OCT2020 is recorded under Illness Visit Day 3,5,28 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Dec 2020 04:49:13 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10,12SEP2020 and 05OCT2020 is recorded under Illness Visit Day 3,5,7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM). | (b) (4), (b) (6) | 07 Dec 2020 04:49:01 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 10,12SEP2020 and 05OCT2020 is recorded under Illness Visit Day 3,5,7 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 07 Dec 2020 04:48:49 |
| Signature has been broken. | Linden DeBoer (b) (4) | 03 Dec 2020 17:28:15 |
| | (b) (4) | |
| User entered '10 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 03 Dec 2020 17:28:15 |
| | (b) (4) | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered '8 Sep 2020' | Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| User closed query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession #1F604835500 is reported with 30oct2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Feb 2021 12:00:42 |
| Query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession #1F604835500 is reported with 30oct2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' answered with 'will update in preclarus as date is right in EDC' (Site from DM). | Samantha Wieseler (b) (4) | 10 Feb 2021 14:15:21 |
| User opened query 'Per GCL LAB reconciliation: Saliva: PPD reports Day 5 sample with Accession #1F604835500 is reported with 30oct2020 date of Collection. Please review the Accession # in Preclarus to confirm the correct date and sample label and amend the EDC or Preclarus as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 05 Feb 2021 15:59:04 |
| User accepted default value 'Day 5 (Day 5)' | Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '12 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '14 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '16 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User closed query 'Per GCL Lab Recon: GCL has Saliva samples with dates of 14SEP2020, 16SEP2020, 21SEP2020, and 28SEP2020 yet there is no record with these dates. Please reconcile or clarify.' (Site from DM). | | 12 Nov 2020 06:09:21 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Query 'Per GCL Lab Recon: GCL has Saliva samples with dates of 14SEP2020, 16SEP2020, 21SEP2020, and 28SEP2020 yet there is no record with these dates. Please reconcile or clarify.' answered with 'updated data' (Site from DM). | Kelsey Kelley (b) (4) | 10 Nov 2020 20:23:12 |
| Signature has been broken. | Kelsey Kelley (b) (4) | 10 Nov 2020 20:22:06 |
| User entered '21 Sep 2020' reason for change: Data Entry Error | Kelsey Kelley (b) (4) | 10 Nov 2020 20:22:06 |
| User opened query 'Per GCL Lab Recon: GCL has Saliva samples with dates of 14SEP2020, 16SEP2020, 21SEP2020, and 28SEP2020 yet there is no record with these dates. Please reconcile or clarify.' (Site from DM). | (b) (4), (b) (6) | 23 Oct 2020 08:35:00 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '6 Oct 2020' reason for change: Data Entry Error | Kelsey Kelley (b) (4) | 06 Oct 2020 13:48:25 |
| User entered empty. | Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Signature has been broken. | (b) (4) | 10 Nov 2020 20:22:37 |
| | Kelsey Kelley (b) (4) | 10 Nov 2020 20:22:37 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | 10 Nov 2020 20:22:37 |
| User signature succeeded. | Kelsey Kelley (b) (4) | 10 Nov 2020 20:22:37 |
| | (b) (4) | 10 Nov 2020 20:22:37 |
| User entered 'No (N)' | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | 08 Oct 2020 15:30:25 |
| | Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Signature has been broken. | (b) (4) | 10 Nov 2020 20:22:37 |
| User entered '28 Sep 2020' reason for change: Data Entry Error | Kelsey Kelley (b) (4) | 10 Nov 2020 20:22:37 |
| User signature succeeded. | (b) (4) | 08 Oct 2020 15:30:25 |
| User entered empty. | Keith Vrbicky (b) (4) | 06 Oct 2020 13:47:48 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User closed query 'Per GCL Lab Reconciliation Requery2: Saliva: Data needs to be recorded on the Saliva collection form of EDC as a 30Oct2020 sample is present in Preclarus. Please review Preclarus and if collected for the subject then update the data on the SALIVA Collection form of appropriate visit' (Site from DM). | (b) (4), (b) (6) | 05 Feb 2021 16:00:31 |
| Query 'Per GCL Lab Reconciliation Requery2: Saliva: Data needs to be recorded on the Saliva collection form of EDC as a 30Oct2020 sample is present in Preclarus. Please review Preclarus and if collected for the subject then update the data on the SALIVA Collection form of appropriate visit' answered with 'will update appropriately' (Site from DM). | Samantha Wieseler (b) (4) | 28 Jan 2021 15:14:21 |
| User opened query 'Per GCL Lab Reconciliation Requery2: Saliva: Data needs to be recorded on the Saliva collection form of EDC as a 30Oct2020 sample is present in Preclarus. Please review Preclarus and if collected for the subject then update the data on the SALIVA Collection form of appropriate visit' (Site from DM). | (b) (4), (b) (6) | 25 Jan 2021 07:03:30 |
| User accepted default value 'Day 28 (Day 28)' | Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:22:47 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM). | | 03 Dec 2020 05:23:52 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30OCT2020 is reported under Illness visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). | (b) (4), (b) (6) | 03 Dec 2020 05:20:16 |
| User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 23 Nov 2020 11:51:49 |
| Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' answered with 'ILLNESS VISIT DAY 28 IS CORRECT' (Site from DM). | Russell Herstein (b) (4) (b) (4) | 20 Nov 2020 22:46:45 |
| User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded as Illness Visit Day 28 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please confirm the correct Visit in the response and update EDC or PPD portal as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 06:22:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '6 Oct 2020' | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:47:48 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 3 (Day 3)' | Linden DeBoer (b) (4) (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:50:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 09 Apr 2021 18:06:45 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 06 Apr 2021 19:58:55 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 06 Apr 2021 19:58:55 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | Samantha Wieseler (b) (4) | 06 Apr 2021 19:58:55 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 06 Apr 2021 19:58:12 |
| DataPoint Un-verified. | Samantha Wieseler (b) (4) | 06 Apr 2021 19:58:12 |
| Signature has been broken. | (b) (4) | 06 Apr 2021 19:58:12 |
| User entered empty; reason for change Data Entry Error | Samantha Wieseler (b) (4) | 06 Apr 2021 19:58:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) | 09 Nov 2020 22:46:13 |
| | Linden DeBoer (b) (4) | |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (1)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:50:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 09 Apr 2021 18:06:45 |
| User entered '10 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| | Samantha Wieseler (b) (4) | 06 Apr 2021 19:58:55 |
| DataPoint Un-verified. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 06 Apr 2021 19:58:12 |
| Signature has been broken. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 06 Apr 2021 19:58:12 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| | Samantha Wieseler (b) (4) | 06 Apr 2021 19:58:12 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '10 Sep 2020' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 5 (Day 5)' | Linden DeBoer (b) (4) (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (2)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '12 Sep 2020' | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 7 (Day 7)' | Linden DeBoer (b) (4) (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) | 09 Nov 2020 22:46:13 |
| | Linden DeBoer (b) (4) | |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (3)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '14 Sep 2020' | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 9 (Day 9)' | Linden DeBoer (b) (4) (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (4)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '16 Sep 2020' | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 14 (Day 14)' | Linden DeBoer (b) (4) (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (5)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '21 Sep 2020' | (b) (4) Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 21 (Day 21)' | Linden DeBoer (b) (4) (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (6)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '28 Sep 2020' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:57

[Visit](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User accepted default value 'Day 28 (Day 28)' | Linden DeBoer (b) (4) (b) (4) | 09 Nov 2020 22:46:13 |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:57

[Was Saliva Collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit (4)

Form: Saliva Collection (7)

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:48 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '5 Oct 2020' | (b) (4) Linden DeBoer (b) (4) | 09 Nov 2020 22:46:13 |
| | (b) (4) | |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:13 |
| DataPoint Verified. | | 02 Apr 2021 19:19:58 |
| User closed query 'Per GCL Lab reconciliation Requery : The saliva dates in Visit 1 and visit 4 are overlapping, please review and rectify, else clarify.Thanks' (Site from DM). | | 23 Feb 2021 05:35:06 |
| Query 'Per GCL Lab reconciliation Requery : The saliva dates in Visit 1 and visit 4 are overlapping, please review and rectify, else clarify.Thanks' answered with 'no dates are overlapping' (Site from DM). | Samantha Wieseler (b) (4) (b) (4) | 28 Jan 2021 15:15:46 |
| User opened query 'Per GCL Lab reconciliation Requery : The saliva dates in Visit 1 and visit 4 are overlapping, please review and rectify, else clarify.Thanks' (Site from DM). | (b) (4), (b) (6) | 25 Jan 2021 07:22:45 |
| User closed query 'Per GCL Lab reconciliation Requery : Saliva: Per your response, data on Saliva collection forms of Illness visit 1 and Illness visit 4 is the same as PPD central lab does not report 2 sample collected and only on Day3 to Day28 sample reported. So please amend EDC to remove duplicate entry of the data.' (Site from DM). | (b) (4), (b) (6) | 25 Jan 2021 07:21:16 |
| Query 'Per GCL Lab reconciliation Requery : Saliva: Per your response, data on Saliva collection forms of Illness visit 1 and Illness visit 4 is the same as PPD central lab does not report 2 sample collected and only on Day3 to Day28 sample reported. So please amend EDC to remove duplicate entry of the data.' answered with 'they are not the same date. Visit 1 is 08Sep2020 and Visit 4 is 06Oct2020' (Site from DM). | Samantha Wieseler (b) (4) (b) (4) | 19 Jan 2021 22:37:55 |
| User opened query 'Per GCL Lab reconciliation Requery : Saliva: Per your response, data on Saliva collection forms of Illness visit 1 and Illness visit 4 is the same as PPD central lab does not report 2 sample collected and only on Day3 to Day28 sample reported. So please amend EDC to remove duplicate entry of the data.' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 07:29:43 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User closed query 'Per GCL Lab reconciliation : Saliva: Data recorded on the Saliva Collection form (Day3 10Sep20- Day28 6Oct20) of this Illness visit 1 is overlapping with the Illness visit 4 Saliva Collection data (Day3 10Sep20- Day 28 5Oct20). Please review and amend the data to avoid duplicating. Thank you. ' (Site from DM). Query 'Per GCL Lab reconciliation : Saliva: Data recorded on the Saliva Collection form (Day3 10Sep20- Day28 6Oct20) of this Illness visit 1 is overlapping with the Illness visit 4 Saliva Collection data (Day3 10Sep20- Day 28 5Oct20). Please review and amend the data to avoid duplicating. Thank you. ' answered with 'correct as entered, data not duplicated' (Site from DM). | (b) (4), (b) (6) | 19 Jan 2021 07:29:43 |
| User opened query 'Per GCL Lab reconciliation : Saliva: Data recorded on the Saliva Collection form (Day3 10Sep20- Day28 6Oct20) of this Illness visit 1 is overlapping with the Illness visit 4 Saliva Collection data (Day3 10Sep20- Day 28 5Oct20). Please review and amend the data to avoid duplicating. Thank you. ' (Site from DM). Query 'Per GCL Lab reconciliation : Saliva: Data recorded on the Saliva Collection form (Day3 10Sep20- Day28 5Oct20) of this Illness visit 1 is overlapping with the Illness visit 4 Saliva Collection data (Day3 10Sep20- Day 28 6Oct20). Please review and amend the data to avoid duplicating. Thank you. ' canceled (Site from DM). | Samantha Wieseler (b) (4) | 15 Jan 2021 01:08:39 |
| User opened query 'Per GCL Lab reconciliation : Saliva: Data recorded on the Saliva Collection form (Day3 10Sep20- Day28 6Oct20) of this Illness visit 1 is overlapping with the Illness visit 4 Saliva Collection data (Day3 10Sep20- Day 28 5Oct20). Please review and amend the data to avoid duplicating. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 08:09:33 |
| User opened query 'Per GCL Lab reconciliation : Saliva: Data recorded on the Saliva Collection form (Day3 10Sep20- Day28 5Oct20) of this Illness visit 1 is overlapping with the Illness visit 4 Saliva Collection data (Day3 10Sep20- Day 28 6Oct20). Please review and amend the data to avoid duplicating. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 08:09:03 |
| User opened query 'Per GCL Lab reconciliation : Saliva: Data recorded on the Saliva Collection form (Day3 10Sep20- Day28 5Oct20) of this Illness visit 1 is overlapping with the Illness visit 4 Saliva Collection data (Day3 10Sep20- Day 28 6Oct20). Please review and amend the data to avoid duplicating. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 07 Jan 2021 08:08:40 |
| User closed query 'Per CDM: Data recorded on the Saliva Collection form (Day3 8Sep20- Day28 5Oct20) of this Illness visit is overlapping with the Saliva Collection data (Day3 10Sep20- Day 28 6Oct20). Please review and amend the data to avoid duplicating. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Dec 2020 06:15:50 |

PRODUCTION RELEASE (v12.003
EAB) (1725)

1945 of 2616

US3032171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|--|-----------------------------------|----------------------|
| Query 'Per CDM: Data recorded on the Saliva Collection form (Day3 8Sep20- Day28 5Oct20) of this Illness visit is overlapping with the Saliva Collection data (Day3 10Sep20- Day 28 6Oct20). Please review and amend the data to avoid duplicating. Thank you.' answered with 'data has been updated' (Site from DM). | Linden DeBoer (b) (4) (b) (4) | 03 Dec 2020 17:29:22 |
| User opened query 'Per CDM: Data recorded on the Saliva Collection form (Day3 8Sep20- Day28 5Oct20) of this Illness visit is overlapping with the Saliva Collection data (Day3 10Sep20- Day 28 6Oct20). Please review and amend the data to avoid duplicating. Thank you.' (Site from DM). | (b) (4), (b) (6) | 12 Nov 2020 06:20:28 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:47:40 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:13 |
| DataPoint Verified. | | 02 Apr 2021 19:19:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '8 Sep 2020' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:47:40 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:13 |
| DataPoint Verified. | | 02 Apr 2021 19:19:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Clinic (Clinic)' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:47:40 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|-----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:13 |
| User entered 'SICKD1' | System | 09 Nov 2020 18:47:40 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 24 Nov 2020 18:52:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 24 Nov 2020 18:52:21 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '8 Sep 2020' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 24 Nov 2020 18:52:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '11:05' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| User entered '8 Sep 2020 11:05' | System | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 02 Apr 2021 19:20:10 |
| DataPoint Un-verified. | | 24 Nov 2020 18:53:13 |
| DataPoint Verified. | | 24 Nov 2020 18:52:46 |
| User signature succeeded. | | 10 Nov 2020 21:36:49 |
| User entered '37.0' C | Keith Vrbicky (b) (4) | |
| | (b) (4) | |
| | Chelsie Nutsch (b) (4) | 09 Nov 2020 18:49:31 |
| | (b) (4) | |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 02 Apr 2021 19:20:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Oral (Oral)' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 02 Apr 2021 19:31:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered empty. | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 02 Apr 2021 19:20:16 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '73' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| User entered 'bpm' | System | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 02 Apr 2021 19:20:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '16' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| User entered 'breaths/min' | System | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| DataPoint Verified. | | 02 Apr 2021 19:20:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '128' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| User entered 'mmHg' | System | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:20:24 |
| Signature has been broken indirectly. | System | 24 Mar 2021 15:09:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '63' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| User entered 'mmHg' | System | 09 Nov 2020 18:49:31 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| | | |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:19 |
| | | |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:23 |
| DataPoint Verified. | | 02 Apr 2021 19:20:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:43 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:23 |
| DataPoint Verified. | | 02 Apr 2021 19:20:40 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '8 Sep 2020' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:43 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:57

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:28 |
| DataPoint Verified. | | 02 Apr 2021 19:20:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:55 |

US3032171

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|--|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:28 |
| DataPoint Verified. | | 02 Apr 2021 19:20:44 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '8 Sep 2020' | (b) (4) Chelsie Nutsch (b) (4) (b) (4) | 09 Nov 2020 18:49:55 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:34 |
| User closed query 'Per CDM: it appears there is a Convalescence Visit day 28 recorded yet no Illness Visit Day 1 recorded. Please reconcile and update accordingly or clarify' (Site from DM). | | 11 Nov 2020 04:03:34 |
| Query 'Per CDM: it appears there is a Convalescence Visit day 28 recorded yet no Illness Visit Day 1 recorded. Please reconcile and update accordingly or clarify' answered with 'Illness visit day 1 is recorded already, 08Sep2020' (Site from DM). | Kelsey Kelley (b) (4) | 10 Nov 2020 20:39:53 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 09 Nov 2020 17:35:21 |
| User opened query 'Per CDM: it appears there is a Convalescence Visit day 28 recorded yet no Illness Visit Day 1 recorded. Please reconcile and update accordingly or clarify' (Site from DM). | | 07 Nov 2020 12:45:36 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| | (b) (4) | |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) | 06 Oct 2020 13:38:40 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:34 |
| DataPoint Verified. | | 09 Nov 2020 17:35:25 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '6 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:38:40 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:34 |
| DataPoint Verified. | | 09 Nov 2020 17:37:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Clinic (Clinic)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:38:40 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:34 |
| User entered 'SICKD28' | System | 06 Oct 2020 13:38:40 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '6 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '08:03' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| User entered '6 Oct 2020 08:03' | System | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '36.8' C | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Oral (Oral)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '73' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| User entered 'bpm' | System | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '14' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| User entered 'breaths/min' | System | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Systolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| DataPoint Verified. | | 09 Nov 2020 17:35:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '103' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| User entered 'mmHg' | System | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 25 Mar 2021 14:18:14 |
| Signature has been broken indirectly. | (b) (4) | 24 Mar 2021 15:10:15 |
| DataPoint Verified. | System | 24 Mar 2021 15:10:15 |
| | (b) (4), (b) (6) | 09 Nov 2020 17:35:38 |
| User signature succeeded. | (b) (4) | |
| | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '69' | (b) (4) | |
| | Kelsey Kelley (b) (4) | 06 Oct 2020 13:39:26 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| User entered 'mmHg' | System | 06 Oct 2020 13:39:26 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| | | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:39 |
| | | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:44 |
| DataPoint Verified. | | 09 Nov 2020 17:36:06 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:35 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:44 |
| DataPoint Verified. | | 09 Nov 2020 17:36:06 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '6 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:35 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:57

Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?

| Audit | User | Time (GMT) |
|---|-------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:48 |
| User closed query 'Per GCL Lab Reconciliation: SARS Cov2: Re-Query: Sample dated 06OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you' (Site from DM). | | 23 Nov 2020 06:28:05 |
| Query 'Per GCL Lab Reconciliation: SARS Cov2: Re-Query: Sample dated 06OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you' answered with 'DATA IS CORRECT AS ENTERED' (Site from DM). | Russell Herstein (b) (4) (b) (4) | 20 Nov 2020 00:19:08 |
| User opened query 'Per GCL Lab Reconciliation: SARS Cov2: Re-Query: Sample dated 06OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 08:10:54 |
| User closed query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 06OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). | (b) (4), (b) (6) | 19 Nov 2020 08:10:54 |
| Query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 06OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'data is added' (Site from DM). | Russell Herstein (b) (4) (b) (4) | 18 Nov 2020 21:49:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 17:36:34 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:57

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation: SARS Cov2: Sample dated 06OCT2020 is recorded under Convalescence visit Day 28 in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM). User signature succeeded. | (b) (4), (b) (6) (b) (4) | 28 Oct 2020 10:04:44 |
| | Keith Vrbicky (b) (4) (b) (4) | 08 Oct 2020 15:30:25 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:42 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 01 May 2021 14:07:48 |
| DataPoint Verified. | | 09 Nov 2020 17:36:34 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Oct 2020 15:30:25 |
| User entered '6 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 06 Oct 2020 13:39:42 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|--|
| User closed query 'Per GCL LAB reconciliation: Saliva Re-query : Please note that the "Saliva collection form" which is reported under this visit "Illness Visit Day 4 " is duplicate entry of the "Illness Visit Day 1". Hence please remove the duplicate data from the saliva collection from at this "Illness Visit Day 4 " and inform CRA to inactive the page accordingly.' (Site from DM). | (b) (4), (b) (6) | 08 Apr 2021 07:02:40 |
| Query 'Per GCL LAB reconciliation: Saliva Re-query Samantha Wieseler : Please note that the "Saliva collection form" which is reported under this visit "Illness Visit Day 4 " is duplicate entry of the "Illness Visit Day 1". Hence please remove the duplicate data from the saliva collection from at this "Illness Visit Day 4 " and inform CRA to inactive the page accordingly.' answered with 'will remove' (Site from DM). DataPoint Verified. | (b) (4) (b) (4), (b) (6) | (b) (4) 06 Apr 2021 19:57:22 02 Apr 2021 19:25:50 |
| User opened query 'Per GCL LAB reconciliation: Saliva Re-query : Please note that the "Saliva collection form" which is reported under this visit "Illness Visit Day 4 " is duplicate entry of the "Illness Visit Day 1". Hence please remove the duplicate data from the saliva collection from at this "Illness Visit Day 4 " and inform CRA to inactive the page accordingly.' (Site from DM). | | 01 Apr 2021 07:55:11 |
| User closed query 'Per GCL LAB reconciliation: Saliva: Please note that the Saliva collection form which is reported under this visit "Illness Visit Day 4 " is duplicate entry of the "Illness Visit Day 1". Hence please remove the duplicate data from the saliva collection from and inform CRA to inactive the page accordingly.' (Site from DM). | (b) (4), (b) (6) | 01 Apr 2021 07:53:59 |
| Query 'Per GCL LAB reconciliation: Saliva: Please note that the Saliva collection form which is reported under this visit "Illness Visit Day 4 " is duplicate entry of the "Illness Visit Day 1". Hence please remove the duplicate data from the saliva collection from and inform CRA to inactive the page accordingly.' answered with 'this was the convalescent visit for the Illness Day 1 visit' (Site from DM). | Linden DeBoer (b) (4) (b) (4) | 22 Mar 2021 20:58:38 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| User opened query 'Per GCL LAB reconciliation: Saliva: Please note that the Saliva collection form which is reported under this visit "Illness Visit Day 4" is duplicate entry of the "Illness Visit Day 1". Hence please remove the duplicate data from the saliva collection from and inform CRA to inactive the page accordingly.' (Site from DM). User signature succeeded. | (b) (4), (b) (6) | 18 Mar 2021 07:11:53 |
| | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:41:29 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:50 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '6 Oct 2020' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:41:29 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:50 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Clinic (Clinic)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Nov 2020 22:41:29 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------|--------|----------------------|
| User entered 'SICKD28' | System | 09 Nov 2020 22:41:29 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User closed query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | (b) (4) | 10 Nov 2020 22:21:56 |
| Query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System). | System | 10 Nov 2020 22:21:56 |
| User entered '6 Oct 2020' reason for change: Data Entry Error | Kelsey Kelley (b) (4) | 10 Nov 2020 22:21:56 |
| User opened query 'The Vital Signs Date is not equal to Visit Date. Please review and reconcile.' (Site from System). | (b) (4) | 09 Nov 2020 22:41:29 |
| User entered '6 Nov 2020' | System | 09 Nov 2020 22:41:29 |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '08:03' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|--------|----------------------|
| User entered '6 Oct 2020 08:03' | System | 10 Nov 2020 22:21:56 |
| User entered '6 Nov 2020 08:03' | System | 09 Nov 2020 22:37:45 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '36.8' C | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered 'Oral (Oral)' | (b) (4) Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered empty. | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '73' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|--------|----------------------|
| User entered 'bpm' | System | 09 Nov 2020 22:37:45 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '14' | Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|--------|----------------------|
| User entered 'breaths/min' | System | 09 Nov 2020 22:37:45 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| User entered '103' | (b) (4) Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 09 Nov 2020 22:37:45 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Diastolic Blood Pressure (xxx)

| Audit | User | Time (GMT) |
|---------------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:25:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 25 Mar 2021 14:18:14 |
| Signature has been broken indirectly. | (b) (4) | 24 Mar 2021 15:10:15 |
| User signature succeeded. | System | 24 Mar 2021 15:10:15 |
| | Keith Vrbicky (b) (4) | 17 Nov 2020 15:50:57 |
| | (b) (4) | |
| User entered '69' | Linden DeBoer (b) (4) | 09 Nov 2020 22:37:45 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered 'mmHg' | System | 09 Nov 2020 22:37:45 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:17 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) | 09 Nov 2020 22:41:40 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:17 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '6 Oct 2020' | (b) (4) Linden DeBoer (b) (4) | 09 Nov 2020 22:41:40 |
| | (b) (4) | |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:57

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) | 09 Nov 2020 22:42:08 |

US3032171

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 11 Aug 2021 21:58:57

[Date of Collection](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:26:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '6 Oct 2020' | (b) (4) Linden DeBoer (b) (4) | 09 Nov 2020 22:42:08 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:26:17 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:21:37 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:26:17 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '9 Jan 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:21:37 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:26:17 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Clinic (Clinic)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:21:37 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'UNBLND_DECIDE' | System | 09 Jan 2021 19:21:37 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Date of updated informed consent \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:35:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '9 Jan 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:22:32 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Mar 2021 21:13:54 |
| User entered '0' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 12:06:25 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Was the participant unblinded?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:35:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User closed query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System). | (b) (4) (b) (4), (b) (6) | 11 Jan 2021 11:15:19 |
| Query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' answered with 'Subject did not receive second vaccination due to being positive for Covid-19' (Site from System). | Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:23:01 |
| User opened query 'Was the participant unblinded is Yes however, data is missing. Please reconcile.' (Site from System). | System | 09 Jan 2021 19:22:32 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:22:32 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Under what version of the Protocol was the Participant unblinded?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Mar 2021 21:13:54 |
| User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537 | (b) (4) | 10 Mar 2021 16:55:28 |
| Amendment Manager inserted this DataPoint. | System | 06 Mar 2021 12:06:25 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

Date of unblinding (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:35:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '9 Jan 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:22:32 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Participant randomization assignment](#)

| Audit | User | Time (GMT) |
|----------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:35:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Placebo (Placebo)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:22:32 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Actual Dose 1](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:35:11 |
| Amendment Manager: User entered 'Placebo (Placebo)' | System | 20 Jan 2021 06:51:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Placebo (Placebo)' | (b) (4) | |
| | Kelsey Kelley (b) (4) | 09 Jan 2021 19:22:32 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Actual Dose 2](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:35:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| Signature has been broken. | (b) (4) Kelsey Kelley (b) (4) | 09 Feb 2021 22:16:48 |
| User entered 'Not Administered (NA)' reason for change: New Information | (b) (4) Kelsey Kelley (b) (4) | 09 Feb 2021 22:16:48 |
| User signature succeeded. | (b) (4) Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered empty; reason for change Data Entry Error | (b) (4) Linden DeBoer (b) (4) | 09 Jan 2021 19:29:41 |
| User entered 'Placebo (Placebo)' reason for change: Data Entry Error | (b) (4) Linden DeBoer (b) (4) | 09 Jan 2021 19:28:06 |
| User entered empty; reason for change Data Entry Error | (b) (4) Linden DeBoer (b) (4) | 09 Jan 2021 19:27:54 |
| User entered 'Placebo (Placebo)' reason for change: Data Entry Error | (b) (4) Linden DeBoer (b) (4) | 09 Jan 2021 19:27:21 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:22:32 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Will participant receive mRNA-1273?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:35:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Jan 2021 19:22:32 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Placebo Only Flag](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '1' | System | 09 Feb 2021 22:16:48 |
| User entered empty. | System | 09 Jan 2021 19:29:41 |
| User entered '1' | System | 09 Jan 2021 19:28:06 |
| User entered empty. | System | 09 Jan 2021 19:27:54 |
| User entered '1' | System | 09 Jan 2021 19:27:21 |
| User entered empty. | System | 09 Jan 2021 19:22:32 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Aug 2021 21:58:57

[Continuing with mRNA-1273](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'I' | System | 09 Feb 2021 22:16:48 |
| User entered empty. | System | 09 Jan 2021 19:29:41 |
| User entered 'I' | System | 09 Jan 2021 19:28:06 |
| User entered empty. | System | 09 Jan 2021 19:27:54 |
| User entered 'I' | System | 09 Jan 2021 19:27:21 |
| User entered empty. | System | 09 Jan 2021 19:22:32 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Height](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered missing code ND - Not Done. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Weight](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered missing code ND - Not Done. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

BMI (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint set to visible. | System | 09 Feb 2021 22:16:48 |
| DataPoint set to invisible. | System | 09 Jan 2021 19:29:41 |
| User entered empty. | System | 09 Jan 2021 19:29:20 |
| DataPoint set to visible. | System | 09 Jan 2021 19:28:06 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Height](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered missing code ND - Not Done. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Weight](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered missing code ND - Not Done. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

BMI (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint set to visible. | System | 09 Feb 2021 22:16:48 |
| DataPoint set to invisible. | System | 09 Jan 2021 19:29:41 |
| User entered empty. | System | 09 Jan 2021 19:29:20 |
| DataPoint set to visible. | System | 09 Jan 2021 19:28:06 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Linden DeBoer (b) (4) | 09 Jan 2021 19:29:20 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '9 Jan 2021' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '11:27' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '9 Jan 2021 11:27' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Temperature (xxx.x)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '36.9' C | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Oral (Oral)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered empty. | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Jan 2021 19:29:20 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '67' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'bpm' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '16' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'breaths/min' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '101' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Jan 2021 19:29:20 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '78' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Height](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered missing code ND - Not Done. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Weight](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered missing code ND - Not Done. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

BMI (xxx.x)

| Audit | User | Time (GMT) |
|-----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint set to visible. | System | 09 Feb 2021 22:16:48 |
| DataPoint set to invisible. | System | 09 Jan 2021 19:29:41 |
| User entered empty. | System | 09 Jan 2021 19:29:20 |
| DataPoint set to visible. | System | 09 Jan 2021 19:28:06 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '9 Jan 2021' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '13:15' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Jan 2021 19:29:20 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '9 Jan 2021 13:15' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '36.7' C | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Oral (Oral)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered empty. | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Jan 2021 19:29:20 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '70' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'bpm' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '16' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'breaths/min' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '103' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '85' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 09 Jan 2021 19:29:20 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:28 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '9 Jan 2021' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:28 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:27:45 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered empty. | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Jan 2021 19:27:45 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered empty. | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:27:45 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the study treatment? \(Unblinded\)](#)

| Audit | User | Time (GMT) |
|-----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint set to visible. | System | 09 Feb 2021 22:16:48 |
| DataPoint set to invisible. | System | 09 Jan 2021 19:29:41 |
| DataPoint set to visible. | System | 09 Jan 2021 19:28:06 |
| DataPoint set to invisible. | System | 09 Jan 2021 19:27:54 |
| User entered 'mRNA-1273' | System | 09 Jan 2021 19:27:45 |
| DataPoint set to visible. | System | 09 Jan 2021 19:27:21 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

What was the treatment date? (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '9 Jan 2021' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:27:45 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '12:45' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:27:45 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '9 Jan 2021 12:45' | System | 09 Jan 2021 19:27:45 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:27:45 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:39:42 |
| User entered 'ONCE' | System | 09 Jan 2021 19:27:45 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'INTRAMUSCULAR' | System | 09 Jan 2021 19:27:45 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:47:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:26:54 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM). | | 20 Apr 2021 05:31:43 |
| Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' answered with '1F617654423' (Site from DM). | Samantha Wieseler (b) (4) (b) (4) | 09 Apr 2021 13:17:50 |
| User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 09JAN2021 is recorded under Participant Decision Visit OL-D1/OL-1 visit in EDC, however the same is missing in PPD Central Lab. Please provide sample Accession number and tracking details in query response to confirm with GCL records. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 09:52:15 |
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:47:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '9 Jan 2021' | Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:26:54 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:47:47 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '10:59' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:26:54 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '9 Jan 2021 10:59' | System | 09 Jan 2021 19:26:54 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:47:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:27:07 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:57

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted, thank you. Kindly consider keeping this query in "Open" state until this missing sample issue is resolved or as soon as you are able to provide the Accession No: and Shipment tracking details. ' (Site from DM). | | 22 Apr 2021 05:10:03 |
| Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted, thank you. Kindly consider keeping this query in "Open" state until this missing sample issue is resolved or as soon as you are able to provide the Accession No: and Shipment tracking details. ' answered with '1F617654423' (Site from DM). | Samantha Wieseler (b) (4) | 09 Apr 2021 13:17:20 |
| User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted, thank you. Kindly consider keeping this query in "Open" state until this missing sample issue is resolved or as soon as you are able to provide the Accession No: and Shipment tracking details. ' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 06:48:53 |
| User closed query 'Per GCL Lab Reconciliation requery: Swab: Per response, "will update when update is available."; however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' (Site from DM). | (b) (4), (b) (6) | 07 Apr 2021 06:48:53 |
| Query 'Per GCL Lab Reconciliation requery: Swab: Per response, "will update when update is available."; however, corresponding updates are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' answered with 'no update available at the time. will update edc with tracking number and ship date when more information is available. ' (Site from DM). | Samantha Wieseler (b) (4) | 22 Mar 2021 18:18:38 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:57

Collection date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| User opened query 'Per GCL Lab Reconciliation requery: Swab: Per response, "will update when update is available."; however, corresponding update are not reflected in Preclarus portal. Kindly consider providing accession, tracking number and shipped date. Thank you.' (Site from DM). DataPoint Verified. | (b) (4), (b) (6) | 18 Mar 2021 10:10:08 |
| User closed query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 09JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM). | | 10 Mar 2021 18:47:55 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 09JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' answered with 'will update when available' (Site from DM). | Samantha Wieseler (b) (4) | 11 Feb 2021 06:02:08 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 09JAN2021 under Participant Decision Visit / OL-D1 in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM). | (b) (4), (b) (6) | 10 Feb 2021 14:13:57 |
| Query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 09JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' canceled (Site from DM). | (b) (4), (b) (6) | 05 Feb 2021 07:55:56 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 09JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM). | | 05 Feb 2021 07:55:38 |
| User opened query 'Per GCL Lab Reconciliation: Swab: Sample Collection date is recorded as 09JAN2021 under Covid-19 Assessment in EDC, however same is missing in PPD central lab. Please reconcile the data and amend GCL or Preclarus as appropriate. Thank you.' (Site from DM). | | 05 Feb 2021 07:51:16 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:57

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| | (b) (4) | |
| User entered '9 Jan 2021' | Linden DeBoer (b) (4) | 09 Jan 2021 19:27:07 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:57

Collection time (00:00 - 23:59)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:47:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered '11:11' | (b) (4) | |
| | Linden DeBoer (b) (4) | 09 Jan 2021 19:27:07 |
| | (b) (4) | |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 21:58:57

[Collection Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '9 Jan 2021 11:11' | System | 09 Jan 2021 19:27:07 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:53:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 18 Jan 2021 19:28:13 |
| User entered 'Yes (Y)' | (b) (4) Linden DeBoer (b) (4) (b) (4) | 09 Jan 2021 19:29:34 |

US3032171

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'I' | System | 09 Jan 2021 19:29:34 |

US3032171

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:54:03 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:15:06 |

US3032171

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:54:03 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '18 Jan 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:15:06 |

US3032171

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:54:03 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:15:06 |

US3032171

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:54:03 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:15:06 |

US3032171

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:54:06 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:15:10 |

US3032171

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'I' | System | 09 Feb 2021 22:15:10 |

US3032171

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[OLD29 Placebo Flag](#)

| Audit | User | Time (GMT) |
|---------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '1' | System | 09 Feb 2021 22:15:10 |
| DataPoint set to visible. | System | 09 Feb 2021 22:15:10 |

US3032171

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:55:25 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:15:30 |

US3032171

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:55:25 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '9 Feb 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:15:30 |

US3032171

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:55:25 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Clinic (Clinic)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:15:30 |

US3032171

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'OLD29' | System | 09 Feb 2021 22:15:30 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Height](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered missing code ND - Not Done. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Weight](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered missing code ND - Not Done. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Height](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered missing code ND - Not Done. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Weight](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered missing code ND - Not Done. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User accepted default value 'Pre-Dose (PREDOSE)' | Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '9 Feb 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '11:01' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '9 Feb 2021 11:01' | System | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '37.2' C | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Oral (Oral)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '70' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'bpm' | System | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '16' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'breaths/min' | System | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '111' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '74' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Height](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered missing code ND - Not Done. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 21:58:57

[Weight](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered missing code ND - Not Done. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:09 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Timepoint](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User accepted default value 'Post-Dose (POSTDOSE)' | Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Date of assessment (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '9 Feb 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

Time of assessment (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '12:22' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '9 Feb 2021 12:22' | System | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '37.0' C | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Oral (Oral)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '64' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'bpm' | System | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '16' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'breaths/min' | System | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '124' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '84' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 09 Feb 2021 22:18:39 |

US3032171

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:16:57 |

US3032171

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:56:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '9 Feb 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:16:57 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Was study treatment given?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:14 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[If No, reason not given](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:14 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:14 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the study treatment?](#)

| Audit | User | Time (GMT) |
|-------------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'MRNA-1273 OR PLACEBO' | System | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the treatment date? \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:14 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '9 Feb 2021' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the treatment time? \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:14 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered '11:49' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Treatment Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '9 Feb 2021 11:49' | System | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[Which arm was used to give treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:14 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Left Arm (LEFT ARM)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the frequency of the study treatment dosing?](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:14 |
| User entered 'ONCE' | System | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Aug 2021 21:58:57

[What was the route of administration for the study treatment?](#)

| Audit | User | Time (GMT) |
|------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'INTRAMUSCULAR' | System | 09 Feb 2021 22:17:15 |

US3032171

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 12 Feb 2021 19:55:23 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 09 Feb 2021 22:17:26 |

US3032171

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'I' | System | 09 Feb 2021 22:17:26 |

US3032171

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Was Contact Attempted?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Yes (Y)' | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Mar 2021 23:18:50 |
| | (b) (4) | |

US3032171

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

Date of Contact or Contact Attempt (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered '16 Feb 2021' | (b) (4) Samantha Wieseler (b) (4) (b) (4) | 08 Mar 2021 23:18:50 |

US3032171

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Please select one status for the follow-up contact](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Contact Made (CONTACT MADE)' | (b) (4) Samantha Wieseler (b) (4) (b) (4) | 08 Mar 2021 23:18:50 |

US3032171

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 21:58:57

[Comments](#)

If Contact Not Made, please provide Comments

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered empty. | (b) (4) Samantha Wieseler (b) (4) (b) (4) | 08 Mar 2021 23:18:50 |

US3032171

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Is the participant continuing to the next visit?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| DataPoint Verified. | | 10 Mar 2021 18:58:57 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Mar 2021 15:35:52 |
| User entered 'Yes (Y)' | (b) (4) Samantha Wieseler (b) (4) (b) (4) | 08 Mar 2021 23:18:54 |

US3032171

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Aug 2021 21:58:57

[Continuing Flag](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'I' | System | 08 Mar 2021 23:18:54 |

US3032171

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was this visit performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:14 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:38 |

US3032171

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Visit date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:14 |
| User entered '19 Mar 2021' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:38 |

US3032171

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Was visit performed at the participant's home or at the clinic?](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:14 |
| User entered 'Clinic (Clinic)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:38 |

US3032171

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 21:58:57

[Folder OID](#)

| Audit | User | Time (GMT) |
|----------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'OLD57' | System | 19 Mar 2021 16:23:38 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Were vital signs assessed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

Date of assessment (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered '19 Mar 2021' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Time of assessment \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered '10:15' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Vital Signs Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '19 Mar 2021 10:15' | System | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Temperature \(xxx.x\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered '36.9' C | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Route of measurement](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered 'Oral (Oral)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[If Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered '66' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Pulse units](#)

| Audit | User | Time (GMT) |
|--------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'bpm' | System | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered '17' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Respiratory Rate units](#)

| Audit | User | Time (GMT) |
|----------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'breaths/min' | System | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered '97' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Systolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure \(xxx\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:18 |
| User entered '65' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Diastolic Blood Pressure units](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered 'mmHg' | System | 19 Mar 2021 16:23:59 |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Height \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| | | |

US3032171

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 21:58:57

[Weight \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| | | |

US3032171

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

[Was the physical examination performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:23 |
| User entered 'No (N)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:24:08 |

US3032171

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 21:58:57

Date of examination (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:23 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:24:08 |

US3032171

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Was the sample collected?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:28 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:24:20 |

US3032171

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

Collection date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:28 |
| User entered '19 Mar 2021' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:24:20 |

US3032171

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:40:28 |
| User entered '10:25' | Kelsey Kelley (b) (4) (b) (4) | 19 Mar 2021 16:24:20 |

US3032171

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 21:58:57

[Collection date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 25 Apr 2021 09:27:05 |
| User entered '19 Mar 2021 10:25' | System | 19 Mar 2021 16:24:20 |

US3032171

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 21:58:57

[Did the participant experience any adverse events?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 12:48:00 |
| DataPoint Verified. | | 09 Nov 2020 18:04:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' reason for change: Data Entry Error | (b) (4) | |
| | Linden DeBoer (b) (4) | 21 Sep 2020 19:14:16 |
| | (b) (4) | |
| User entered 'No (N)' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:23:23 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[AEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:10 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:50:59 |
| User entered 'USA-US032-2020-mRNA-1273-P301000005' | System | 22 Sep 2020 13:50:54 |
| User entered 'New' | (b) (4), (b) (6) | 22 Sep 2020 13:50:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| User closed query 'PV Query: Please update event term to COVID-19.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 16:51:11 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 15:46:41 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 09 Oct 2020 15:46:41 |
| Data point term sent to Coder | System | 09 Oct 2020 15:45:15 |
| Query 'PV Query: Please update event term to COVID-19.' answered with 'data updated' (Site from Safety). | Linden DeBoer (b) (4) (b) (4) | 09 Oct 2020 15:44:55 |
| Coding entries removed. | Linden DeBoer (b) (4) (b) (4) | 09 Oct 2020 15:44:43 |
| Signature has been broken. | Linden DeBoer (b) (4) (b) (4) | 09 Oct 2020 15:44:43 |
| User entered 'COVID-19' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 09 Oct 2020 15:44:43 |
| User opened query 'PV Query: Please update event term to COVID-19.' (Site from Safety). | (b) (4), (b) (6) | 09 Oct 2020 14:19:20 |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Oct 2020 01:01:27 |
| User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 08 Oct 2020 01:01:27 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 05 Oct 2020 16:14:54 |
| User closed query 'PV Query: Please update event term to COVID-19.' (Site from Safety). | (b) (4), (b) (6) | 05 Oct 2020 13:48:47 |
| Data point term sent to Coder | System | 01 Oct 2020 17:28:02 |
| Query 'PV Query: Please update event term to COVID-19.' answered with 'data updated' (Site from Safety). | Linden DeBoer (b) (4) (b) (4) | 01 Oct 2020 17:27:21 |
| Coding entries removed. | Linden DeBoer (b) (4) (b) (4) | 01 Oct 2020 17:27:10 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Signature has been broken. | Linden DeBoer (b) (4) | 01 Oct 2020 17:27:10 |
| | (b) (4) | |
| User entered 'SARS-COV-2 INFECTION- COVID-19' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 01 Oct 2020 17:27:10 |
| | (b) (4) | |
| User opened query 'PV Query: Please update event term to COVID-19.' (Site from Safety). | (b) (4), (b) (6) | 28 Sep 2020 19:41:22 |
| | | |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: SARS-CoV-2 infection - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Sep 2020 19:18:52 |
| | (b) (4) | |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Sep 2020 19:18:52 |
| | (b) (4) | |
| Data point term sent to Coder | System | 21 Sep 2020 19:17:45 |
| User entered 'sars-cov-2 infection' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:16 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:42:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| User closed query 'PV Query: Since the symptom started on 05-SEP-2020, please reconsider the start date.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 16:07:01 |
| Query 'PV Query: Since the symptom started on 05-SEP-2020, please reconsider the start date.' answered with 'updated' (Site from Safety). | Samantha Wieseler (b) (4) | 08 Dec 2020 18:42:14 |
| DataPoint Un-verified. | (b) (4) | |
| Signature has been broken. | Samantha Wieseler (b) (4) | 08 Dec 2020 18:42:05 |
| User entered '05 Sep 2020' reason for change: Data Entry Error | (b) (4) | |
| User opened query 'PV Query: Since the symptom started on 05-SEP-2020, please reconsider the start date.' (Site from Safety). | Samantha Wieseler (b) (4) | 08 Dec 2020 18:42:05 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:20 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 20:03:19 |
| User entered '10 Sep 2020' reason for change: Data Entry Error | | 04 Nov 2020 20:03:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| User closed query 'PV Query: Please consider updating start date of the event to the date of onset of symptoms and date positive test was collected (per records, 08 Sep 2020).' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 05 Oct 2020 13:48:49 |
| Query 'PV Query: Please consider updating start date of the event to the date of onset of symptoms and date positive test was collected (per records, 08 Sep 2020).' answered with 'data updated' (Site from Safety). | Linden DeBoer (b) (4) | 02 Oct 2020 16:34:41 |
| Signature has been broken. | (b) (4) | |
| User entered '08 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 02 Oct 2020 16:34:34 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User opened query 'PV Query: Please consider updating start date of the event to the date of onset of symptoms and date positive test was collected (per records, 08 Sep 2020).' (Site from Safety). User signature succeeded. | (b) (4), (b) (6) (b) (4) | 28 Sep 2020 19:40:43 |
| | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '10 Sep 2020' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:23 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:24 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | (b) (4) | 02 Oct 2020 16:34:50 |
| Signature has been broken. | System | 02 Oct 2020 16:34:50 |
| User entered 'No (N)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 02 Oct 2020 16:34:50 |
| User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System). | (b) (4) | 02 Oct 2020 16:34:50 |
| User signature succeeded. | Linden DeBoer (b) (4) | 02 Oct 2020 16:34:34 |
| User entered 'Yes (Y)' | System | 02 Oct 2020 16:34:34 |
| | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | 21 Sep 2020 19:16:54 |
| | Kelsey Kelley (b) (4) | |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:27 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 20:03:19 |
| User entered '24 Sep 2020' reason for change: Data Entry Error | | 04 Nov 2020 20:03:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 05 Oct 2020 13:48:52 |
| Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'data updated' (Site from Safety). | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:34:57 |
| Signature has been broken. | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:34:34 |
| User entered '10 Sep 2020' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:34:34 |
| User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). | (b) (4), (b) (6) | 28 Sep 2020 19:40:35 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Severity](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:29 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 20:03:19 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error | | 04 Nov 2020 20:03:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) System | 21 Sep 2020 19:31:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 19:31:27 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 21 Sep 2020 19:31:27 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 19:16:54 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 21 Sep 2020 19:31:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 19:31:27 |
| User entered 'No (N)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 21 Sep 2020 19:31:27 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 21 Sep 2020 19:16:54 |
| User entered empty. | System | 21 Sep 2020 19:16:54 |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:40 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:42 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:45 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:50 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:52 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:55 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:06:58 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:00 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| User closed query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 05 Oct 2020 13:48:55 |
| Query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' answered with 'data updated' (Site from Safety). | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:35:04 |
| Signature has been broken. | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:34:34 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:34:34 |
| User opened query 'PV Query: Please provide the investigator's rationale for assessing the event as related to the study drug.' (Site from Safety). | (b) (4), (b) (6) | 28 Sep 2020 19:40:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | System | 21 Sep 2020 19:31:36 |
| User entered 'Related (RELATED)' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 21 Sep 2020 19:31:36 |
| User closed query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 19:31:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 19:31:27 |
| User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System). | System | 21 Sep 2020 19:31:27 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 21 Sep 2020 19:31:27 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 19:16:54 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:03 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | 21 Sep 2020 19:31:27 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 19:31:27 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 21 Sep 2020 19:31:27 |
| User opened query 'Data is required. Please complete.' (Site from System). | (b) (4) | 21 Sep 2020 19:16:54 |
| User entered empty. | System | 21 Sep 2020 19:16:54 |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

Action taken with investigational product

| Audit | User | Time (GMT) |
|---|--------------------------|----------------------|
| User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System). | (b) (4), (b) (6) | 19 Nov 2020 05:28:47 |
| Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'DOSE WITHHELD DUE TO COVID-19 INFECTION' (Site from System). | Russell Herstein (b) (4) | 18 Nov 2020 23:07:15 |
| User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System). | System | 10 Nov 2020 20:15:42 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:05 |
| User closed query 'Per DM CLR-RQ: Site's response noted. However, Dosing Discontinuation page or End of Study/Study Discontinuation page does not reflect this information. Please update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 06 Nov 2020 11:39:26 |
| Query 'Per DM CLR-RQ: Site's response noted. However, Dosing Discontinuation page or End of Study/Study Discontinuation page does not reflect this information. Please update applicable eCRFs as appropriate. Otherwise, clarify.' answered with 'Dosing discontinuation page added' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 20:07:06 |
| User opened query 'Per DM CLR-RQ: Site's response noted. However, Dosing Discontinuation page or End of Study/Study Discontinuation page does not reflect this information. Please update applicable eCRFs as appropriate. Otherwise, clarify.' (Site from DM). | (b) (4), (b) (6) | 24 Oct 2020 22:12:32 |
| User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify.' (Site from DM). | (b) (4), (b) (6) | 24 Oct 2020 22:12:32 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

Action taken with investigational product

| Audit | User | Time (GMT) |
|--|-------------------------------------|----------------------|
| Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' answered with 'CORRECT AS ENTERED, SUBJECT DID NOT RECEIVE SECOND VACCINE' (Site from DM). | Russell Herstein (b) (4) (b) (4) | 21 Oct 2020 02:01:00 |
| User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in treatment discontinuation if applicable. Review and update. Else, clarify. ' (Site from DM). | (b) (4), (b) (6) (b) (4) | 19 Oct 2020 05:44:25 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Investigational Product Withdrawn (WITHDRAWN)' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'I' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:15 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Outcome](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:17 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 05 Oct 2020 13:48:56 |
| Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'data updated' (Site from Safety). | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:35:11 |
| Signature has been broken. | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:34:34 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:34:34 |
| User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). | (b) (4), (b) (6) | 28 Sep 2020 19:40:03 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:16:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Narrative](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Apr 2021 19:42:11 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| User closed query 'PV Query: Please confirm that subject's COVID-19 test on 08 Sep 2020 was negative. Please provide the date the subject tested positive for COVID-19.' (Site from Safety). | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 16:06:40 |
| Query 'PV Query: Please confirm that subject's COVID-19 test on 08 Sep 2020 was negative. Please provide the date the subject tested positive for COVID-19.' answered with 'updated' (Site from Safety). | Samantha Wieseler (b) (4) | 08 Dec 2020 18:45:13 |
| DataPoint Un-verified. | (b) (4) | 08 Dec 2020 18:45:06 |
| Signature has been broken. | Samantha Wieseler (b) (4) | 08 Dec 2020 18:45:06 |
| User entered 'subjects test was positive 08Sep2020' reason for change: Data Entry Error | (b) (4) | 08 Dec 2020 18:45:06 |
| User opened query 'PV Query: Please confirm that subject's COVID-19 test on 08 Sep 2020 was negative. Please provide the date the subject tested positive for COVID-19.' (Site from Safety). | (b) (4), (b) (6) | 04 Dec 2020 23:32:37 |
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:07:20 |
| User closed query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' (Site from Safety). | (b) (4), (b) (6) | 05 Oct 2020 13:49:01 |
| User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | (b) (4), (b) (6) | 05 Oct 2020 13:49:00 |
| User closed query 'PV Query: Please confirm if two tests were performed on 08 Sep 2020 (with one being negative), or if one test was performed which resulted on 16 Sep 2020.' (Site from Safety). | (b) (4), (b) (6) | 05 Oct 2020 13:48:58 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Narrative](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Query 'PV Query: Please confirm if two tests were performed on 08 Sep 2020 (with one being negative), or if one test was performed which resulted on 16 Sep 2020.' answered with 'only 1 test. ' (Site from Safety). | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:37:09 |
| Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'rest. no dr visit or medications to treat' (Site from Safety). | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:36:52 |
| Query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' answered with 'no' (Site from Safety). | Linden DeBoer (b) (4) (b) (4) | 02 Oct 2020 16:35:37 |
| User opened query 'PV Query: Did the subject have any known exposure to COVID-19 or risk factors?' (Site from Safety). | (b) (4), (b) (6) | 28 Sep 2020 19:41:08 |
| User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety). | | 28 Sep 2020 19:40:57 |
| User opened query 'PV Query: Please confirm if two tests were performed on 08 Sep 2020 (with one being negative), or if one test was performed which resulted on 16 Sep 2020.' (Site from Safety). | | 28 Sep 2020 19:40:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 21 Sep 2020 19:31:27 |

US3032171

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Aug 2021 21:58:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 21 Sep 2020 19:16:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[AEID](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| | | |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Adverse event](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | (b) (4) | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Angioedema and urticaria, HLT: Urticarias, PT: Urticaria, LLT: Generalized urticaria - version MedDRA\\23.0. | (b) (4) Coder Import (b) (4) | 21 Sep 2020 19:19:42 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) | 21 Sep 2020 19:19:42 |
| Data point term sent to Coder | System | 21 Sep 2020 19:18:47 |
| User entered 'generalized urticaria' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '13 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:12:00 |
| DataPoint Un-verified. | | 02 Dec 2020 20:11:58 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) | 21 Sep 2020 19:17:54 |
| | Kelsey Kelley (b) (4) | |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| User entered empty. | System | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 20:12:46 |
| User entered 'No (N)' reason for change: New Information | | 04 Nov 2020 20:12:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | (b) (4) | |
| Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System). | System | 04 Nov 2020 20:13:16 |
| User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System). | System | 04 Nov 2020 20:12:46 |
| Signature has been broken. | (b) (4), (b) (6) | 04 Nov 2020 20:12:46 |
| User entered '24 Sep 2020' reason for change: New Information | | 04 Nov 2020 20:12:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:17:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

End time (00:00-23:59)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| User entered empty. | System | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | (b) (4) | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 20:12:46 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error | (b) (4) | 04 Nov 2020 20:12:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) System | 21 Sep 2020 19:32:11 |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 19:32:11 |
| User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error | Linden DeBoer (b) (4) (b) (4) | 21 Sep 2020 19:32:11 |
| User opened query 'Data is required. Please complete.' (Site from System). | System | 21 Sep 2020 19:17:54 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 19:32:11 |
| User entered 'No (N)' reason for change: Data Entry Error | System | 21 Sep 2020 19:32:11 |
| User opened query 'Data is required. Please complete.' (Site from System). | Linden DeBoer (b) (4) | 21 Sep 2020 19:32:11 |
| User entered empty. | (b) (4) | |
| | System | 21 Sep 2020 19:17:54 |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:17:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 19:32:11 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | System | 21 Sep 2020 19:32:11 |
| User opened query 'Data is required. Please complete.' (Site from System). | Linden DeBoer (b) (4) | 21 Sep 2020 19:32:11 |
| User entered empty. | (b) (4) | |
| | System | 21 Sep 2020 19:17:54 |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:17:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Data is required. Please complete.' (Site from System). | (b) (4) | |
| Query 'Data is required. Please complete.' answered by data change (Site from System). | System | 21 Sep 2020 19:32:11 |
| User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error | System | 21 Sep 2020 19:32:11 |
| User opened query 'Data is required. Please complete.' (Site from System). | Linden DeBoer (b) (4) | 21 Sep 2020 19:32:11 |
| User entered empty. | (b) (4) | |
| | System | 21 Sep 2020 19:17:54 |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:17:54 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Not Applicable (NOT APPLICABLE)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'l' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Outcome](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| Signature has been broken. | (b) (4) (u), (v), (b) (6) | 04 Nov 2020 20:13:16 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information | | 04 Nov 2020 20:13:16 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| DataPoint Verified. | | 02 Dec 2020 20:11:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| User entered '0' | System | 21 Sep 2020 19:32:11 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| User entered '1' | System | 21 Sep 2020 19:17:54 |

US3032171

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Aug 2021 21:58:57

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 17:30:01 |
| | | |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Adverse event](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain in hip - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 31 Mar 2021 15:19:01 |
| User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. | Coder Import (b) (4) (b) (4) | 31 Mar 2021 15:19:01 |
| Data point term sent to Coder | System | 31 Mar 2021 15:18:45 |
| User entered 'right hip pain' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Was this a medically-attended AE?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Was this a Solicited Adverse Reaction?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'No (N)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'No (N)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '17 Mar 2021' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

(

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Start time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[AE start date and time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, end date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 22 Apr 2021 21:48:49 |
| Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System). | System | 22 Apr 2021 21:48:49 |
| User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). | System | 22 Apr 2021 21:48:40 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[End time \(00:00-23:59\)](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[AE End Date and Time \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Severity](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'Grade 2/Moderate (Grade 2/Moderate)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Is the adverse event serious?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'No (N)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '0' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:18:18 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '0' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:18:18 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '0' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

Hospital Admission Date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

Hospital Discharge Date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Admitted to ICU?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Number of Days in ICU](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '0' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:18:18 |
| | (b) (4) | |

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US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '0' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '0' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Relationship to investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'Not Related (NOT RELATED)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Relationship to Study Procedure](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'Not Related (NOT RELATED)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Action taken with investigational product](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'Not Applicable (NOT APPLICABLE)' | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[None](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '0' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:18:18 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Concomitant Medication](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'I' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:18:18 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Concomitant Procedure](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered '0' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:18:18 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Outcome](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:15:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: | (b) (4) | |
| Data Entry Error | Samantha Wieseler (b) (4) | 22 Apr 2021 21:48:49 |
| DataPoint Un-verified. | (b) (4) | |
| Signature has been broken. | Samantha Wieseler (b) (4) | 22 Apr 2021 21:48:40 |
| User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: | (b) (4) | |
| Data Entry Error | Samantha Wieseler (b) (4) | 22 Apr 2021 21:48:40 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:18:18 |
| | (b) (4) | |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Narrative](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Apr 2021 19:41:48 |
| User entered empty. | Kelsey Kelley (b) (4) (b) (4) | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '0' | System | 31 Mar 2021 15:18:18 |

US3032171

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Aug 2021 21:58:57

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered 'I' | System | 31 Mar 2021 15:18:18 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 21:58:57

[Were any prior/concomitant medications and/or vaccinations taken?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 03 May 2021 12:48:00 |
| DataPoint Verified. | | 09 Nov 2020 18:07:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:23:35 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 17 Sep 2020 03:56:41 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 17 Sep 2020 03:56:41 |
| Data point term sent to Coder | System | 16 Sep 2020 23:36:52 |
| Coding entries removed. | Kelsey Kelley (b) (4) | 16 Sep 2020 23:36:26 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 17 Aug 2020 02:27:26 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 17 Aug 2020 02:27:26 |
| Data point term sent to Coder | System | 11 Aug 2020 15:27:16 |
| User entered 'Montelukast sodium' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 17 Sep 2020 09:26:50 |
| Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' answered with 'data updated' (Site from DM). | Kelsey Kelley (b) (4) (b) (4) | 16 Sep 2020 23:36:33 |
| User entered 'MEDICAL HISTORY: EXERCISE-INDUCED ASTHMA' reason for change: Data Entry Error | Kelsey Kelley (b) (4) (b) (4) | 16 Sep 2020 23:36:26 |
| User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF. ' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 03:54:13 |
| User entered 'medical history:' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '10' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'mg (mg)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'once daily (QD)' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Oral (ORAL)' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 16:07:29 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 11 Aug 2020 15:26:16 |
| User entered 'un UNK 2010' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 15:26:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT HFA - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 06:42:19 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 14 Aug 2020 06:42:19 |
| Data point term sent to Coder | System | 11 Aug 2020 15:27:17 |
| User entered 'flovent HFA' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'medical history: exercise-induced asthma' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '110' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Signature has been broken. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:10 |
| User entered 'ug (ug)' reason for change: Data Entry Error | (b) (4) | |
| | Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:10 |
| User signature succeeded. | (b) (4) | |
| | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Other (OTHER)' | (b) (4) | |
| | Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User closed query 'Per CDM: Please note that ug (for microgram) is one of the available options from the dropdown list provided for Dose unit. Please review, reconcile and update as appropriate. Thank you. ' (Site from DM). | | 11 Nov 2020 04:00:35 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Query 'Per CDM: Please note that ug (for microgram) is one of the available options from the dropdown list provided for Dose unit. Please review, reconcile and update as appropriate. Thank you. ' answered with 'updated' (Site from DM). | (b) (4) | |
| Signature has been broken. | Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:14 |
| User entered empty; reason for change Data Entry Error | (b) (4) | |
| User opened query 'Per CDM: Please note that ug (for microgram) is one of the available options from the dropdown list provided for Dose unit. Please review, reconcile and update as appropriate. Thank you. ' (Site from DM). | Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:10 |
| User signature succeeded. | (b) (4) | |
| User entered 'mcg' | (b) (4), (b) (6) | 06 Nov 2020 08:24:00 |
| | | |
| | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| | Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:16:05 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Dec 2020 19:47:17 |
| DataPoint Un-verified. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Dec 2020 18:38:12 |
| Signature has been broken. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Dec 2020 18:38:12 |
| User entered 'once daily (QD)' reason for change: | (b) (4) | |
| Data Entry Error | Samantha Wieseler (b) (4) | 08 Dec 2020 18:38:12 |
| DataPoint Verified. | (b) (4) | |
| | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered 'every other day (QOD)' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 16:07:43 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 11 Aug 2020 15:27:07 |
| User entered 'un UNK 2010' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 08 Dec 2020 18:38:12 |
| User entered '2' | System | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 15:27:07 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Aug 2020 16:42:12 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 11 Aug 2020 16:42:12 |
| Data point term sent to Coder | System | 11 Aug 2020 15:28:19 |
| User entered 'albuterol inhaler' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'medical history: exercise-induced asthma' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '90' reason for change: Data Entry Error | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:09:51 |
| User entered '2' | (b) (4) | |
| | Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Signature has been broken. | (b) (4) Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:24 |
| User entered 'ug (ug)' reason for change: Data Entry Error | (b) (4) Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:24 |
| User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable (i.e. ug). ' (Site from DM). | (b) (4), (b) (6) | 20 Oct 2020 12:39:32 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable (i.e. ug). ' answered with 'data updated' (Site from DM). | (b) (4) Linden DeBoer (b) (4) | 08 Oct 2020 18:01:22 |
| Signature has been broken. | (b) (4) Linden DeBoer (b) (4) | 08 Oct 2020 18:01:12 |
| User entered 'Other (OTHER)' reason for change: Data Entry Error | Linden DeBoer (b) (4) | 08 Oct 2020 18:01:12 |
| User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable (i.e. ug). ' (Site from DM). | (b) (4), (b) (6) | 08 Oct 2020 04:55:52 |
| Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable (i.e. mcg). ' canceled (Site from DM). | | 08 Oct 2020 04:55:31 |
| User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable (i.e. mcg). ' (Site from DM). | | 08 Oct 2020 04:55:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 11:25:39 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'data updated' (Site from DM). | Kelsey Kelley (b) (4) | 21 Sep 2020 19:10:01 |
| User entered 'mg (mg)' reason for change: Data Entry Error | Kelsey Kelley (b) (4) | 21 Sep 2020 19:09:51 |
| User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puff as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 15 Sep 2020 03:54:46 |
| User entered 'puff (PUFF)' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User closed query 'Per CDM: Please note that ug (for microgram) is one of the available options from the dropdown list provided for Dose unit. Please review and update as appropriate. Thank you. ' (Site from DM). | | 11 Nov 2020 04:00:46 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Query 'Per CDM: Please note that ug (for microgram) is one of the available options from the dropdown list provided for Dose unit. Please review and update as appropriate. Thank you. ' answered with 'updated' (Site from DM). | (b) (4) Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:28 |
| Signature has been broken. | (b) (4) Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:24 |
| User entered empty; reason for change Data Entry Error | (b) (4) Kelsey Kelley (b) (4) | 10 Nov 2020 20:17:24 |
| User opened query 'Per CDM: Please note that ug (for microgram) is one of the available options from the dropdown list provided for Dose unit. Please review and update as appropriate. Thank you. ' (Site from DM). | (b) (4), (b) (6) | 06 Nov 2020 08:24:25 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| Signature has been broken. | (b) (4) Linden DeBoer (b) (4) | 08 Oct 2020 18:01:12 |
| User entered 'MCG' reason for change: Data Entry Error | (b) (4) Linden DeBoer (b) (4) | 08 Oct 2020 18:01:12 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'as needed (PRN)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

If frequency is Other, specify

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 16:07:48 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 11 Aug 2020 15:27:43 |
| User entered 'un UNK 2010' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|--------|----------------------|
| User entered empty. | System | 11 Aug 2020 15:27:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

Name of Medication

| Audit | User | Time (GMT) |
|--|-----------------------------|----------------------|
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS AND ESTROGENS IN COMBINATION, PRODUCT: ESTROGENS CONJUGATED;MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: PREMPRO - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Dec 2020 00:54:44 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Dec 2020 00:54:44 |
| Data point term sent to Coder | System | 08 Dec 2020 18:38:56 |
| Coding entries removed. | Samantha Wieseler (b) (4) | 08 Dec 2020 18:38:50 |
| DataPoint Verified. | (b) (4) (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: PROGESTOGENS AND ESTROGENS IN COMBINATION, ATC: PROGESTOGENS AND ESTROGENS, FIXED COMBINATIONS, PRODUCT: ESTROGENS CONJUGATED;MEDROXYPROGESTERONE ACETATE, PRODUCTSYNONYM: PREMPRO - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 17:57:09 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 12 Aug 2020 17:57:09 |
| Data point term sent to Coder | System | 11 Aug 2020 15:29:21 |
| User entered 'prempro' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|---|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 10 Mar 2021 18:16:33 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 08 Dec 2020 19:47:17 |
| DataPoint Un-verified. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Dec 2020 18:38:50 |
| Signature has been broken. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Dec 2020 18:38:50 |
| User entered 'MEDICAL HISTORY: estrogen HORMONE DEFICIENCY' reason for change: Data Entry Error | (b) (4) | |
| | Samantha Wieseler (b) (4) | 08 Dec 2020 18:38:50 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered 'medical history: hormone deficiency' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0.125/5' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'mg (mg)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'once daily (QD)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Oral (ORAL)' | Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System). | (b) (4) (b) (4), (b) (6) | 12 Aug 2020 16:07:55 |
| User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System). | System | 11 Aug 2020 15:28:26 |
| User entered 'un May 2020' | Kelsey Kelley (b) (4) (b) (4) | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 11 Aug 2020 15:28:26 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|---------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) | 22 Sep 2020 05:52:00 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Sep 2020 05:52:00 |
| Data point term sent to Coder | System | 21 Sep 2020 19:12:28 |
| User entered 'prednisone' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'adverse event: generalized urticaria' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '40' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'mg (mg)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'once daily (QD)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Oral (ORAL)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '14 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '17 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

Was this medication taken for solicited event?

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). | | 20 Oct 2020 14:28:39 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' answered with 'data updated' (Site from DM). | (b) (4) Linden DeBoer (b) (4) | 08 Oct 2020 18:02:05 |
| Signature has been broken. | Linden DeBoer (b) (4) | 08 Oct 2020 18:01:52 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4) Linden DeBoer (b) (4) | 08 Oct 2020 18:01:52 |
| User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate.' (Site from DM). | (b) (4) (b) (4), (b) (6) | 08 Oct 2020 09:37:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| User entered '1' | System | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|-------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| User entered '1' | System | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:29 |
| User entered '804 (804)' | System | 21 Sep 2020 19:11:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

Name of Medication

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003. | (b) (4) (b) (4) Coder Import (b) (4) | 19 Oct 2020 20:36:25 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 19 Oct 2020 20:36:25 |
| Data point term sent to Coder | System | 19 Oct 2020 20:35:19 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 05:52:00 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) (b) (4) | 22 Sep 2020 05:52:00 |
| Data point term sent to Coder | System | 21 Sep 2020 19:51:04 |
| DataPoint inactivated with code reason code Data not required. | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:50:04 |
| Data point term sent to Coder | System | 21 Sep 2020 19:13:32 |
| User entered 'prednisone' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered 'adverse event: generalized urticaria' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered '30' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered 'mg (mg)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered 'once daily (QD)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

If frequency is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered 'Oral (ORAL)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered '18 Sep 2020' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | (b) (4) | |
| | System | 19 Oct 2020 20:35:16 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| | (b) (4) | |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 21 Sep 2020 19:12:43 |
| User entered '22 Sep 2020' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:12:43 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate ' (Site from DM). | (b) (4) (b) (4), (b) (6) | 06 Nov 2020 08:48:52 |
| Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' answered with 'entry error. not solicited.' (Site from DM). | (b) (4), (b) (6) | 04 Nov 2020 20:30:11 |
| Signature has been broken. | (b) (4), (b) (6) | 04 Nov 2020 20:29:51 |
| User entered 'No (N)' reason for change: Data Entry Error | (b) (4), (b) (6) | 04 Nov 2020 20:29:51 |
| User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, recorded indication is not a solicited event per protocol. Review and update entry as appropriate. ' (Site from DM). | (b) (4), (b) (6) | 29 Oct 2020 05:40:16 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered 'Yes (Y)' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| | (b) (4) | |
| User entered '1' | System | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| User entered '1' | (b) (4) | |
| | System | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:32 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:16 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:50:04 |
| | (b) (4) | |
| User entered '804 (804)' | System | 21 Sep 2020 19:12:43 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

Name of Medication

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) | 19 Oct 2020 20:36:26 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 19 Oct 2020 20:36:26 |
| Data point term sent to Coder | System | 19 Oct 2020 20:35:18 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Sep 2020 05:52:00 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Sep 2020 05:52:00 |
| Data point term sent to Coder | System | 21 Sep 2020 19:50:03 |
| DataPoint inactivated with code reason code Data not required. | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| Data point term sent to Coder | System | 21 Sep 2020 19:14:33 |
| User entered 'prednisone' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered 'adverse event: generalized urticaria' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered '20' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered 'mg (mg)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered 'once daily (QD)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

If frequency is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered 'Oral (ORAL)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | (b) (4) | |
| | System | 19 Oct 2020 20:35:04 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| | (b) (4) | |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 21 Sep 2020 19:13:33 |
| User entered '23 Sep 2020' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

Start date completely unknown

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). | (b) (4) | |
| | System | 19 Oct 2020 20:35:04 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| | (b) (4) | |
| DataPoint inactivated with code reason code Data not required. | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| | (b) (4) | |
| User opened query 'Future date has been entered. Please correct.' (Site from System). | System | 21 Sep 2020 19:13:33 |
| User entered '28 Sep 2020' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered '1' | (b) (4) | |
| | System | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| User entered '1' | (b) (4) | |
| | System | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:36 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:35:04 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:51 |
| | (b) (4) | |
| User entered '804 (804)' | System | 21 Sep 2020 19:13:33 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

Name of Medication

| Audit | User | Time (GMT) |
|---|------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003. | (b) (4) Coder Import (b) (4) | 19 Oct 2020 20:36:26 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 19 Oct 2020 20:36:26 |
| Data point term sent to Coder | System | 19 Oct 2020 20:35:17 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Sep 2020 05:52:01 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. | Coder Import (b) (4) | 22 Sep 2020 05:52:01 |
| Data point term sent to Coder | System | 21 Sep 2020 19:50:03 |
| DataPoint inactivated with code reason code Data not required. | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| Data point term sent to Coder | System | 21 Sep 2020 19:14:33 |
| User entered 'prednisone' | Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered 'adverse event: generalized urticaria' | Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered '10' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered 'mg (mg)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

If dose unit is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered 'once daily (QD)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

If frequency is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered 'Oral (ORAL)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

If route of administration is Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|---|--|--|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| User closed query 'Per the source this medication began on 14SEP20 please update to reflect the source' (Site from CRA). DataPoint Verified. | (b) (4) | 13 Apr 2021 15:28:42 13 Apr 2021 15:28:30 |
| Query 'Per the source this medication began on 14SEP20 please update to reflect the source' answered with 'prednisone happens at a tapered rate each one is started and stopped on a different date.' (Site from CRA). User opened query 'Per the source this medication began on 14SEP20 please update to reflect the source' (Site from CRA). User signature succeeded. | Samantha Wieseler (b) (4) (b) (4) (b) (4), (b) (6) | 15 Mar 2021 18:12:05 10 Mar 2021 18:19:05 08 Dec 2020 19:47:17 |
| User entered '29 Sep 2020' reason for change: Data Entry Error DataPoint Un-verified. | Samantha Wieseler (b) (4) (b) (4) Samantha Wieseler (b) (4) | 08 Dec 2020 18:40:12 08 Dec 2020 18:39:49 08 Dec 2020 18:39:49 |
| Signature has been broken. | (b) (4) Samantha Wieseler (b) (4) | 08 Dec 2020 18:39:49 |
| User entered '23 Sep 2020' reason for change: Data Entry Error DataPoint Verified. | Samantha Wieseler (b) (4) (b) (4) (b) (4), (b) (6) | 08 Dec 2020 18:39:49 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 22 Oct 2020 14:49:33 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). DataPoint activated with code reason code Data required. DataPoint inactivated with code reason code Data not required. | System Kelsey Kelley (b) (4) (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:34:58 19 Oct 2020 20:34:58 21 Sep 2020 19:49:57 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). User entered '29 Sep 2020' | System Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:14:32 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

Start date completely unknown

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|--|--|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| User closed query 'Per the source this medication was discontinued by the subject on 17SEP20 please update or clarify ' (Site from CRA). DataPoint Verified. | (b) (4) | 13 Apr 2021 15:29:30 13 Apr 2021 15:29:28 |
| Query 'Per the source this medication was discontinued by the subject on 17SEP20 please update or clarify ' answered with 'prednisone happens at a tapered rate each one is started and stopped on a different date. ' (Site from CRA). User opened query 'Per the source this medication was discontinued by the subject on 17SEP20 please update or clarify ' (Site from CRA). User signature succeeded. | Samantha Wieseler (b) (4) (b) (4) (b) (4), (b) (6) | 15 Mar 2021 18:12:09 10 Mar 2021 18:19:55 08 Dec 2020 19:47:17 |
| User entered '05 Oct 2020' reason for change: Data Entry Error DataPoint Un-verified. | Samantha Wieseler (b) (4) (b) (4) Samantha Wieseler (b) (4) | 08 Dec 2020 18:40:12 08 Dec 2020 18:39:49 |
| Signature has been broken. | (b) (4) Samantha Wieseler (b) (4) | 08 Dec 2020 18:39:49 |
| User entered '28 Sep 2020' reason for change: Data Entry Error DataPoint Verified. | Samantha Wieseler (b) (4) (b) (4) (b) (4), (b) (6) | 08 Dec 2020 18:39:49 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) (b) (4) | 22 Oct 2020 14:49:33 |
| User closed query 'Future date has been entered. Please correct.' (Site from System). DataPoint activated with code reason code Data required. DataPoint inactivated with code reason code Data not required. | System Kelsey Kelley (b) (4) (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:34:58 19 Oct 2020 20:34:58 21 Sep 2020 19:49:57 |
| User opened query 'Future date has been entered. Please correct.' (Site from System). User entered '05 Oct 2020' | System Kelsey Kelley (b) (4) (b) (4) | 21 Sep 2020 19:14:32 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| DataPoint activated with code reason code Data required. | (b) (4) Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered '1' | (b) (4) | |
| | System | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| User entered '1' | (b) (4) | |
| | System | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:38 |
| DataPoint activated with code reason code Data required. | Kelsey Kelley (b) (4) | 19 Oct 2020 20:34:58 |
| DataPoint inactivated with code reason code Data not required. | (b) (4) | |
| | Kelsey Kelley (b) (4) | 21 Sep 2020 19:49:57 |
| | (b) (4) | |
| User entered '804 (804)' | System | 21 Sep 2020 19:14:32 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Name of Medication](#)

| Audit | User | Time (GMT) |
|---|--------------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003. | (b) (4) (b) (4) Coder Import (b) (4) | 19 Oct 2020 20:40:29 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 19 Oct 2020 20:40:29 |
| Data point term sent to Coder | System | 19 Oct 2020 20:39:29 |
| User entered 'seasonal influenza vaccine' | Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|---|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'prophylaxis for seasonal influenza' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '0.5' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'mL (mL)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|----------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'once (ONCE)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'Intramuscular (INTRAMUSCULAR)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

Start date (dd MMM yyyy)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 20:26:22 |
| User entered '07 Oct 2020' reason for change: Data Entry Error | | 04 Nov 2020 20:26:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '09 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '0' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|--|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| Signature has been broken. | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 20:26:22 |
| User entered '07 Oct 2020' reason for change: Data Entry Error | | 04 Nov 2020 20:26:22 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered '09 Oct 2020' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|---|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| DataPoint Verified. | | 02 Dec 2020 20:13:31 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 22 Oct 2020 14:49:33 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) (b) (4) | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| User entered empty. | System | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| User entered empty. | System | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|---------------------|------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 30 Apr 2021 23:23:42 |
| User entered empty. | System | 19 Oct 2020 20:39:16 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Mar 2021 15:20:05 |
| User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 31 Mar 2021 15:20:05 |
| Data point term sent to Coder | System | 31 Mar 2021 15:19:49 |
| User entered 'ibuprofen' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered 'right hip pain' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered '800' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered 'mg (mg)' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered 'three times daily (TID)' | (b) (4) Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered 'Oral (ORAL)' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered empty. | Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered '17 Mar 2021' | (b) (4) Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered '0' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered 'Yes (Y)' | (b) (4) Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered empty. | (b) (4) Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:48:13 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Apr 2021 15:36:09 |
| User entered 'No (N)' | Kelsey Kelley (b) (4) | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '3' | System | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 31 Mar 2021 15:19:40 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Name of Medication](#)

| Audit | User | Time (GMT) |
|--|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: COXIBS, PRODUCT: CELECOXIB, PRODUCTSYNONYM: CELEBREX - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Apr 2021 01:54:39 |
| User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. | Coder Import (b) (4) | 23 Apr 2021 01:54:39 |
| Data point term sent to Coder | System | 22 Apr 2021 21:50:00 |
| User entered 'celebrex' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Prophylaxis](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered 'No (N)' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Indication](#)

| Audit | User | Time (GMT) |
|-------------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered 'right hip pain' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Dose per administration](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered '200' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Dose unit](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered 'mg (mg)' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[If dose unit is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered empty. | (b) (4) Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Frequency](#)

| Audit | User | Time (GMT) |
|--------------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered 'once daily (QD)' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[If frequency is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered empty. | (b) (4) Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Route of administration](#)

| Audit | User | Time (GMT) |
|----------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered 'Oral (ORAL)' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[If route of administration is Other, specify](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered empty. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Start date \(dd MMM yyyy\)](#)

| Audit | User | Time (GMT) |
|----------------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered '20 Apr 2021' | (b) (4) Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Start date completely unknown](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered '0' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Ongoing?](#)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered 'Yes (Y)' | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

If not Ongoing, End date (*dd MMM yyyy*)

| Audit | User | Time (GMT) |
|---------------------------|---------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered empty. | (b) (4) | |
| | Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |
| | (b) (4) | |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Was this medication taken for solicited event?](#)

| Audit | User | Time (GMT) |
|---------------------------|--------------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 28 Apr 2021 17:06:18 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 23 Apr 2021 19:37:07 |
| User entered 'No (N)' | (b) (4) Samantha Wieseler (b) (4) | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Separate Dosage Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Unit Number \(derived\)](#)

| Audit | User | Time (GMT) |
|------------------|--------|----------------------|
| User entered '1' | System | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 21:58:57

[Interval Dosage Definition \(derived\)](#)

| Audit | User | Time (GMT) |
|--------------------------|--------|----------------------|
| User entered '804 (804)' | System | 22 Apr 2021 21:49:46 |

US3032171

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 21:58:57

[Were any concomitant procedures performed?](#)

| Audit | User | Time (GMT) |
|---------------------------|----------------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 02 Dec 2020 20:13:15 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'No (N)' | (b) (4) Kelsey Kelley (b) (4) | 11 Aug 2020 15:28:37 |
| | (b) (4) | |

US3032171

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:58:57

Date of dosing discontinuation (dd MMM yyyy)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 04:59:15 |
| DataPoint Verified. | | 15 Apr 2021 14:46:35 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User entered '21 Sep 2020' | (b) (4) (b) (4), (b) (6) | 04 Nov 2020 20:06:38 |

US3032171

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:58:57

[Primary reason for dosing discontinuation](#)

| Audit | User | Time (GMT) |
|---|-----------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 04:59:15 |
| DataPoint Verified. | | 15 Apr 2021 14:46:35 |
| User closed query 'Per CDM: Please review and verify if the Primary reason for dosing discontinuation could be recorded as "Due to SARS-COV-2" from the dropdown list provided as per page 42 of CCGs v2.0. Kindly update as appropriate, else clarify. ' (Site from DM). User signature succeeded. | | 11 Nov 2020 04:01:17 |
| | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| | (b) (4) | |
| Query 'Per CDM: Please review and verify if the Primary reason for dosing discontinuation could be recorded as "Due to SARS-COV-2" from the dropdown list provided as per page 42 of CCGs v2.0. Kindly update as appropriate, else clarify. ' answered with 'data updated' (Site from DM). | Kelsey Kelley (b) (4) | 10 Nov 2020 20:16:18 |
| | (b) (4) | |
| User entered 'Due to SARS-COV-2 (COVID)' reason for change: Data Entry Error | Kelsey Kelley (b) (4) | 10 Nov 2020 20:15:42 |
| | (b) (4) | |
| User opened query 'Per CDM: Please review and verify if the Primary reason for dosing discontinuation could be recorded as "Due to SARS-COV-2" from the dropdown list provided as per page 42 of CCGs v2.0. Kindly update as appropriate, else clarify. ' (Site from DM). User entered 'SAE (specify) (SAE)' | (b) (4), (b) (6) | 06 Nov 2020 13:57:00 |
| | | 04 Nov 2020 20:06:38 |

US3032171

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 21:58:57

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

| Audit | User | Time (GMT) |
|--|----------------------------------|----------------------|
| Data hard locked. | (b) (4), (b) (6) | 29 Apr 2021 04:59:15 |
| DataPoint Verified. | | 15 Apr 2021 14:46:35 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Nov 2020 21:36:49 |
| User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System). | (b) (4) System | 10 Nov 2020 20:16:10 |
| User entered empty; reason for change Data Entry Error | Kelsey Kelley (b) (4) (b) (4) | 10 Nov 2020 20:16:10 |
| User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System). | System | 10 Nov 2020 20:15:42 |
| User entered 'Sars-CoV-2 Infection' | (b) (4), (b) (6) | 04 Nov 2020 20:06:38 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'USA-US032-2020-MRNA-1273-P301000005' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Keith' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Vrbicky' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:16 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '1410 N 13th St, Suite 5' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:18 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'Norfolk' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:20 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'NE' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:22 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '68701' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| Reviewed for Safety. | | 05 Oct 2020 13:49:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'US' | (b) (4) System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| | (b) (4) | |
| Signature has been broken. | System | 09 Dec 2020 16:09:56 |
| User entered '5' | System | 09 Dec 2020 16:09:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| | (b) (4) | |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered '4' | System | 19 Nov 2020 18:30:00 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| | (b) (4) | |
| Signature has been broken. | System | 12 Oct 2020 16:52:53 |
| User entered '3' | System | 12 Oct 2020 16:52:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| | (b) (4) | |
| Signature has been broken. | System | 05 Oct 2020 13:49:19 |
| User entered '2' | System | 05 Oct 2020 13:49:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '1' | System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'USA-US032-2020-MRNA-1273-P301000005' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Keith' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Vrbicky' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:16 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '1410 N 13th St, Suite 5' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 1 Dec 2020 18:37:18 |
| Reviewed for Safety. | | 9 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'Norfolk' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:20 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'NE' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:22 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '68701' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| Reviewed for Safety. | | 05 Oct 2020 13:49:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'US' | (b) (4) System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| | (b) (4) | |
| Signature has been broken. | System | 09 Dec 2020 16:09:56 |
| User entered '5' | System | 09 Dec 2020 16:09:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| | (b) (4) | |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered '4' | System | 19 Nov 2020 18:30:00 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| | (b) (4) | |
| Signature has been broken. | System | 12 Oct 2020 16:52:53 |
| User entered '3' | System | 12 Oct 2020 16:52:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| | (b) (4) | |
| Signature has been broken. | System | 05 Oct 2020 13:49:19 |
| User entered '2' | System | 05 Oct 2020 13:49:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '1' | System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:58:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered '22/Sep/2020 09:51' | (b) (4) System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 11 Aug 2021 21:58:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| Reviewed for Safety. | | 05 Oct 2020 13:49:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'USA-US032-2020-MRNA-1273-P301000005' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Keith' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Vrbicky' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: Street

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:16 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '1410 N 13th St, Suite 5' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: City](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:18 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'Norfolk' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:20 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'NE' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:22 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '68701' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| Reviewed for Safety. | | 05 Oct 2020 13:49:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'US' | (b) (4) System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| | (b) (4) | |
| Signature has been broken. | System | 09 Dec 2020 16:09:56 |
| User entered '5' | System | 09 Dec 2020 16:09:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| | (b) (4) | |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered '4' | System | 19 Nov 2020 18:30:00 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| | (b) (4) | |
| Signature has been broken. | System | 12 Oct 2020 16:52:53 |
| User entered '3' | System | 12 Oct 2020 16:52:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| | (b) (4) | |
| Signature has been broken. | System | 05 Oct 2020 13:49:19 |
| User entered '2' | System | 05 Oct 2020 13:49:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '1' | System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:58:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| User entered '05/Oct/2020 09:49' | (b) (4) System | 05 Oct 2020 13:49:19 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 11 Aug 2021 21:58:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| Reviewed for Safety. | | 12 Oct 2020 16:52:43 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| User entered 'l' | (b) (4) (b) (4), (b) (6) | 05 Oct 2020 13:49:19 |
| | | |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'USA-US032-2020-MRNA-1273-P301000005' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Keith' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Vrbicky' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:16 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '1410 N 13th St, Suite 5' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:18 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'Norfolk' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: State](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:20 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'NE' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: Postal Code](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:22 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '68701' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| Reviewed for Safety. | | 05 Oct 2020 13:49:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'US' | (b) (4) System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| | (b) (4) | |
| Signature has been broken. | System | 09 Dec 2020 16:09:56 |
| User entered '5' | System | 09 Dec 2020 16:09:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| | (b) (4) | |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered '4' | System | 19 Nov 2020 18:30:00 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| | (b) (4) | |
| Signature has been broken. | System | 12 Oct 2020 16:52:53 |
| User entered '3' | System | 12 Oct 2020 16:52:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| | (b) (4) | |
| Signature has been broken. | System | 05 Oct 2020 13:49:19 |
| User entered '2' | System | 05 Oct 2020 13:49:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '1' | System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:58:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| User entered '12/Oct/2020 12:52' | (b) (4) System | 12 Oct 2020 16:52:53 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 11 Aug 2021 21:58:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 12 Oct 2020 16:52:53 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'USA-US032-2020-MRNA-1273-P301000005' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Keith' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Vrbicky' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:16 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '1410 N 13th St, Suite 5' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:18 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'Norfolk' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:20 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 9 Nov 2020 18:29:44 |
| DataPoint Verified. | | 9 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'NE' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:22 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '68701' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| Reviewed for Safety. | | 05 Oct 2020 13:49:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'US' | (b) (4) System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| | (b) (4) | |
| Signature has been broken. | System | 09 Dec 2020 16:09:56 |
| User entered '5' | System | 09 Dec 2020 16:09:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| | (b) (4) | |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered '4' | System | 19 Nov 2020 18:30:00 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| | (b) (4) | |
| Signature has been broken. | System | 12 Oct 2020 16:52:53 |
| User entered '3' | System | 12 Oct 2020 16:52:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| | (b) (4) | |
| Signature has been broken. | System | 05 Oct 2020 13:49:19 |
| User entered '2' | System | 05 Oct 2020 13:49:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '1' | System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:58:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:47:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| User entered '19/Nov/2020 13:29' | (b) (4) System | 19 Nov 2020 18:30:00 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 11 Aug 2021 21:58:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 5 Apr 2021 14:47:37 |
| Reviewed for Safety. | | 9 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 19 Nov 2020 18:30:00 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[SAEID](#)

| Audit | User | Time (GMT) |
|---|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'USA-US032-2020-MRNA-1273-P301000005' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Serious

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Death](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Life threatening](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Requires inpatient or prolongation of existing Hospitalization](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Persistent or significant disability or incapacity](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Congenital anomaly or birth defect](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Other medically important event](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'No (N)' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's First Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Keith' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator's Last Name](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| Reviewed for Safety. | (b) (4) (b) (4), (b) (6) | 22 Sep 2020 13:51:17 |
| User entered 'Vrbicky' | System | 22 Sep 2020 13:50:54 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Site Address: Street](#)

| Audit | User | Time (GMT) |
|--|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 1 Dec 2020 18:37:16 |
| Reviewed for Safety. | | 9 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '1410 N 13th St, Suite 5' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: City

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:18 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'Norfolk' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: State

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:20 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered 'NE' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

Site Address: Postal Code

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 21 Dec 2020 18:37:22 |
| Reviewed for Safety. | | 09 Dec 2020 16:09:41 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| Un-reviewed for Safety. | (b) (4) | |
| DataPoint Un-verified. | System | 19 Nov 2020 18:30:00 |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered empty. | System | 19 Nov 2020 18:30:00 |
| Reviewed for Safety. | (b) (4), (b) (6) | 19 Nov 2020 18:29:44 |
| DataPoint Verified. | | 09 Nov 2020 18:04:38 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 06 Nov 2020 17:45:55 |
| User entered '68701' | (b) (4) | |
| | (b) (4), (b) (6) | 04 Nov 2020 20:14:32 |
| | | |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[Investigator Country](#)

| Audit | User | Time (GMT) |
|---------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 09 Nov 2020 18:04:38 |
| Reviewed for Safety. | | 05 Oct 2020 13:49:09 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| User entered 'US' | (b) (4) System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 11 Aug 2021 21:58:57

[E2B Transmit Flag \(Derived/Hidden\)](#)

| Audit | User | Time (GMT) |
|----------------------------|-----------------------|----------------------|
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| | (b) (4) | |
| Signature has been broken. | System | 09 Dec 2020 16:09:56 |
| User entered '5' | System | 09 Dec 2020 16:09:56 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 20 Nov 2020 16:29:49 |
| | (b) (4) | |
| Signature has been broken. | System | 19 Nov 2020 18:30:00 |
| User entered '4' | System | 19 Nov 2020 18:30:00 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 13 Oct 2020 13:52:19 |
| | (b) (4) | |
| Signature has been broken. | System | 12 Oct 2020 16:52:53 |
| User entered '3' | System | 12 Oct 2020 16:52:53 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 05 Oct 2020 16:14:54 |
| | (b) (4) | |
| Signature has been broken. | System | 05 Oct 2020 13:49:19 |
| User entered '2' | System | 05 Oct 2020 13:49:19 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 28 Sep 2020 17:21:20 |
| | (b) (4) | |
| User entered '1' | System | 22 Sep 2020 13:51:24 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:58:57

[Date of submission \(Pre-filled from custom function\)](#)

| Audit | User | Time (GMT) |
|----------------------------------|-----------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:47:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| User entered '09/Dec/2020 11:09' | (b) (4) System | 09 Dec 2020 16:09:56 |

US3032171

Folder: SAE USA-US032-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 11 Aug 2021 21:58:57

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

| Audit | User | Time (GMT) |
|---------------------------|-----------------------------|----------------------|
| DataPoint Verified. | (b) (4), (b) (6) | 15 Apr 2021 14:47:37 |
| User signature succeeded. | Keith Vrbicky (b) (4) | 10 Dec 2020 16:21:22 |
| User entered 'I' | (b) (4) (b) (4), (b) (6) | 09 Dec 2020 16:09:56 |