

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Cohort Selection

DO NOT USE THE OPTIONS STAGE 1 NONSENTINEL and STAGE 2 from this CRF. As per protocol amendment 5, STAGE 3 option is equivalent to PHASE 2/3.

| | | |
|----|---|-----------------|
| 1. | Select appropriate response - Protocol version | 24 JUL 2020 |
| 2. | Select appropriate response - What cohort does the subject belong to? | STAGE 3 COHORTS |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

| | |
|--|--|
| Header Text: c4591001 | Form: MAIN INFORMED CONSENT |
| Visit: COHORT_SELECTION | Form Status: Data Complete, Locked, Frozen, Verified |
| Form Version: 22-Apr-2020 21:02 | Site Name: (1097) Main Street Physician's Care - Waterway |
| Site No: 1097 | Subject Initials: --- |
| Subject No: 10971061 | Generated Time (GMT): 29-Mar-2021 10:39 |
| Generated By: (b) (4) | |

[eCRF Audit Trail History](#)

| Informed Consent | | |
|------------------|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/28/2020 |

090177e196ae3e3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [10971061] |
| 2. | Birth Date: | (b) (6) 1953 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Aug/28/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Form Comments

Inclusion Criteria Not Met

| | | |
|----|---|-------------------|
| 1. | Description of Inclusion Criterion Not Met | Not Done _____ |
|----|---|-------------------|

Exclusion Criteria Met

| | | |
|----|---|-------------------|
| 2. | Description of Exclusion Criterion Met | Not Done _____ |
|----|---|-------------------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Aug/28/2020 |
| 2. | Phase of Disposition: | SCREENING |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Medical History Details

| | | |
|-----|---|-------------------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Peripheral Vascular Disease] |
| | Start Date: | Feb/18/2020 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Chronic depression] |
| | Start Date: | Apr/22/2018 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [COPD] |
| | Start Date: | Mar/23/2018 |
| | Ongoing: | YES |
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Fibromyalgia] |
| | Start Date: | Mar/23/2018 |
| | Ongoing: | YES |
| 1.e | Line/MH Number: | [5] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Degenerative Lumbar disc] |
| | Start Date: | Mar/23/2018 |
| | Ongoing: | YES |
| 1.f | Line/MH Number: | [6] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Vit D deficiency] |
| | Start Date: | Mar/23/2018 |
| | Ongoing: | YES |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|---|----------------------|
| 1.g | Line/MH Number: | [7] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [ADHD] |
| | Start Date: | Mar/23/2018 |
| | Ongoing: | YES |
| 1.h | Line/MH Number: | [8] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Anxiety] |
| | Start Date: | Mar/23/2020 |
| | Ongoing: | YES |
| 1.i | Line/MH Number: | [9] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hyperlipidemia] |
| | Start Date: | Mar/23/2018 |
| | Ongoing: | YES |
| 1.j | Line/MH Number: | [10] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hypertension] |
| | Start Date: | Mar/23/2018 |
| | Ongoing: | YES |
| 1.k | Line/MH Number: | [11] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Pulmonary Fibrosis] |
| | Start Date: | Dec/UNK/2015 |
| | Ongoing: | YES |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Aug/28/2020 |
| 2. | Weight: | [135.0] |
| 3. | Unit: | LB |
| 4. | Height: | [65.0] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [22.5] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [97.5] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Form Comments](#)
[eCRF Audit Trail History](#)

Lab Urinalysis

| | | | |
|----|---------------------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Lab Sub-Panel: | Not Applicable _____ | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Laboratory Name and Address (Derived) | Not Applicable _____ [] | Comments |
| 5. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 6.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Not Applicable _____ Choriogonadotropin Beta_PX113 | |
| | Result: | Not Applicable _____ | Comments |
| | Not Done: | Not Applicable _____ | Comments |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: RANDOMIZATION

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Aug/28/2020 |
| 2. | Randomization Number: | [244514] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Aug/28/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN69ZV] |
| 5.b | Sample ID | [BN69ZS] |
| 5.c | Sample ID | [BN69ZT] |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/28/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN6BDC] |
|-----|-----------|----------|

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

| | |
|--|--|
| Header Text: c4591001 | Form: VACCINATION |
| Visit: V1_DAY1_VAX1_L | Form Status: Data Complete, Locked, Frozen, Verified |
| Form Version: 22-Apr-2020 21:04 | Site Name: (1097) Main Street Physician's Care - Waterway |
| Site No: 1097 | Subject Initials: --- |
| Subject No: 10971061 | Generated Time (GMT): 29-Mar-2021 10:39 |
| Generated By: (b) (4) | |

[eCRF Audit Trail History](#)

| Vaccination | | |
|-------------|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Aug/28/2020 13:35 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | THE PROTOCOL SPECIFIED OBSERVATION PERIOD |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3e3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Sep/17/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

| | | |
|-----|---|------------------------------|
| 1. | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO |
| 2.a | Symptom: | FEVER |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.b | Symptom: | FATIGUE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.c | Symptom: | HEADACHE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2 f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.g | Symptom: | NEW OR WORSENERD MUSCLE PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|--|-----------------------------|
| 2.h | Symptom: | NEW OR WORSENEED JOINT PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 3. | Injection Site Location: | DELTOID MUSCLE |
| 4. | Injection Site Body Side: | LEFT |
| 5.a | Injection Site Reaction: | REDNESS |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.b | Injection Site Reaction: | SWELLING |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |
| 5.c | Injection Site Reaction: | PAIN AT INJECTION SITE |
| | Were injection site reactions present on the last day the Subject Diary was completed? | NO |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

| | |
|--|--|
| Header Text: c4591001 | Form: VITAL SIGNS - TEMP |
| Visit: V2_VAX2_L | Form Status: Data Complete, Locked, Frozen, Verified |
| Form Version: 15-Sep-2020 21:54 | Site Name: (1097) Main Street Physician's Care - Waterway |
| Site No: 1097 | Subject Initials: --- |
| Subject No: 10971061 | Generated Time (GMT): 29-Mar-2021 10:39 |
| Generated By: (b) (4) | |

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/17/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [97.9] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Sep/17/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

| | | |
|-----|-------------|-------------------------------|
| 6.a | Sponsor ID: | [113] |
| | Test: | Choriogonadotropin Beta_PX113 |
| | Result: | |
| | Not Done: | NOT DONE |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/17/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BN6B4B] |
|-----|-----------|----------|

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Nov/12/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Vaccination Symptoms Diary - Symptom Resolved Dates

| | | |
|-----|---|-------------------------------|
| 1. | Were medications to treat fever/pain given on the last day the Subject Diary was completed? | NO |
| 2.a | Symptom: | FEVER |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.b | Symptom: | FATIGUE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.c | Symptom: | HEADACHE |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.d | Symptom: | CHILLS |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.e | Symptom: | VOMITING |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.f | Symptom: | DIARRHEA |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |
| 2.g | Symptom: | NEW OR WORSENERED MUSCLE PAIN |
| | Were fever or systemic symptoms present on the last day the Subject Diary was completed? | NO |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Nov/12/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BPVCPH] |
| 5.b | Sample ID | [BPVCPJ] |
| 5.c | Sample ID | [BPVCPK] |
| 5.d | Sample ID | [BL9XR7] |
| 5.e | Sample ID | [BL9XR8] |
| 5.f | Sample ID | [BL9XR9] |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V4_MONTH6_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V5_MONTH12_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V6_MONTH24_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** DATE OF VISIT - ILLNESS ONSET

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Nov/12/2020 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

| | | |
|----|-------------------------|---------|
| 3. | COVID-19 Illness Visit: | COVID_A |
|----|-------------------------|---------|

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Signs and Symptoms

| | | | |
|----|--------------------------------|-------------------------------|--------------------------|
| 1. | Date of Assessment: | Nov/12/2020 | |
| 2. | Date of First Symptom Started: | Not Applicable _____ // | Comments |
| 3. | Symptoms Ongoing? | Not Applicable _____ | Comments |

Symptoms

| | | | |
|-----|----------------------|--------------------------------------|--------------------------|
| 4.a | Symptoms: | FEVER | |
| | Was symptom present? | Not Applicable _____ | Comments |
| 4.b | Symptoms: | NEW OR INCREASED COUGH | |
| | Was symptom present? | NO | |
| 4.c | Symptoms: | NEW OR INCREASED SHORTNESS OF BREATH | |
| | Was symptom present? | NO | |
| 4.d | Symptoms: | CHILLS | |
| | Was symptom present? | NO | |
| 4.e | Symptoms: | NEW OR INCREASED MUSCLE PAIN | |
| | Was symptom present? | NO | |
| 4.f | Symptoms: | NEW LOSS OF TASTE OR SMELL | |
| | Was symptom present? | NO | |
| 4.g | Symptoms: | NEW OR INCREASED SORE THROAT | |
| | Was symptom present? | NO | |
| 4.h | Symptoms: | DIARRHEA | |
| | Was symptom present? | NO | |
| 4.i | Symptoms: | VOMITING | |
| | Was symptom present? | NO | |

Symptoms - Other

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

| | | |
|---|--|--|
| Header Text: c4591001 | | |
| Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 | Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 | |
| Form Version: 10-Oct-2020 16:02 | Form Status: Data Complete, Frozen | |
| Site No: 1097 | Site Name: (1097) Main Street Physician's Care - Waterway | |
| Subject No: 10971061 | Subject Initials: --- | |
| Generated By: (b) (4) | Generated Time (GMT): 29-Mar-2021 10:39 | |

| | |
|----|----------------------------|
| 5. | Symptoms - Other Text: [] |
|----|----------------------------|

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|---------------|------------------------------|----------------------------|-------------|---------------------------------|
| 1. | Not Done | Not Done | Not Done | Not Done | Not Done | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Nov/12/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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Microbiology Specimen

| | | | |
|----|-------------------------------|--------------------------|--------------------------|
| 1. | Actual Date of Collection: | Not Done _____ // | Comments |
| 2. | Specimen Type: | Not Done _____ | Comments |
| 3. | Specimen Collection Location: | Not Done _____ | Comments |
| 4. | Assay Code and Description: | Not Done _____ | Comments |
| 5. | Device Type: | Not Done _____ | Comments |
| 6. | Trade Name: | Not Done _____ | Comments |
| 7. | Test Result: | Not Done _____ | Comments |
| 8. | Comments/Findings/Details: | Not Done _____ [] | Comments |
| 9. | Trade Name Other, Specify: | Not Done _____ [] | Comments |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | NO |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [Patient was in hospital then went to stay with her daughter. We were unable to make contact with her for a brief period of time.] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | | |
|----|--|---|--------------------------|
| 1. | Data Origin | SITE | |
| 2. | Sample Type | NASAL_SWAB | |
| 3. | Sample Collected? | YES Date of Collection: Nov/12/2020 | Comments |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] | |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BPVCPF] |
| 5.b | Sample ID | [] |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

eCRF Audit Trail History

Health Care Utilization

| | | |
|-----|---------------------------------------|---|
| 1.a | Physician or Healthcare Professional: | SPECIALIST |
| | Occurrence of Visits or Contacts: | NO |
| 1.b | Physician or Healthcare Professional: | EMERGENCY ROOM |
| | Occurrence of Visits or Contacts: | YES Number of Visits or Contacts: [1] |
| 1.c | Physician or Healthcare Professional: | PRIMARY CARE PHYSICIAN |
| | Occurrence of Visits or Contacts: | YES Number of Visits or Contacts: [1] |
| 1.d | Physician or Healthcare Professional: | URGENT CARE |
| | Occurrence of Visits or Contacts: | NO |
| 1.e | Physician or Healthcare Professional: | TELEPHONE CONSULTATION |
| | Occurrence of Visits or Contacts: | NO |
| 1.f | Physician or Healthcare Professional: | OTHER |
| | Occurrence of Visits or Contacts: | NO |

Health Care Utilization Other

| | | |
|----|-------------------------------------|-----|
| 2. | Other Type of Practitioner Specify: | [] |
|----|-------------------------------------|-----|

Health Care Utilization

| | | |
|----|--|----|
| 3. | Has the subject been hospitalized due to potential COVID-19 illness? | NO |
|----|--|----|

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Treatment | Start Date | Form Instance |
|----|----------------------|---------------------------------------|----------------|----------------|----------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT
Nov/12/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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Respiratory Treatment

| | | | |
|----|--|-------------------------|--------------------------|
| 1. | What is the treatment Identifier? | Not Applicable _____ | Comments |
| | | [] | |
| 2. | Concomitant Non-drug Treatment Pre-specified: | Not Applicable _____ | Comments |
| 3. | Treatment: | Not Applicable _____ | Comments |
| 4. | Treatment: | Not Applicable _____ | Comments |
| | | [] | |
| 5. | Start Date: | Not Applicable _____ | Comments |
| | | // | |
| 6. | Ongoing? | Not Applicable _____ | Comments |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Form Comments](#)
[eCRF Audit Trail History](#)

Illness Details

| | | | |
|----|--|----------------------------|--------------------------|
| 1. | Category of Clinical Event: | POTENTIAL COVID-19 ILLNESS | Comments |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | NO | Comments |
| 3. | Toxicity Grade: | 0 | Comments |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category of Clinical Event: | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance |
|----|-----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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Illness Details

| | | | |
|----|--------------------------------|-------------------------|--------------------------|
| 1. | Category of Clinical Event: | Not Applicable _____ | Comments |
| 2. | Subcategory of Clinical Event: | Not Applicable _____ | Comments |
| 3. | Was a diagnosis obtained? | Not Applicable _____ | Comments |
| 4. | Toxicity Grade: | Not Applicable _____ | Comments |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|----------------|------------------|----------------|----------------------------|----------------|----------------|---------------------------------|
| | | | | | Sponsor-Defined Identifier | Test: | Result: | |
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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Lab Chemistry Details

| | | | |
|----|-----------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Laboratory Name and Address | Not Applicable _____ [] | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 5.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | C Reactive Protein_PX329 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----------|-----------------------------------|---------------------------------|--------------------------|
| 5.b | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Alanine Aminotransferase_PX30 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |
| 5.c | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Aspartate Aminotransferase_PX28 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----------|-----------------------------------|---------------------------|--------------------------|
| 5.d | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Alkaline Phosphatase_PX35 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.e | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Bilirubin_PX21 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5 f | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Blood Urea Nitrogen_PX47 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.g | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Creatinine_PX48 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Form Version: 21-Aug-2020 02:51
Site No: 1097 **Site Name:** (1097) Main Street Physician's Care - Waterway
Subject No: 10971061 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:39

| # | Category for Lab Test | Vendor Name (DERIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-----------------------|------------------|----------------|----------------------------|----------------|----------------|---------------------------------|
| | | | | | Sponsor-Defined Identifier | Test: | Result: | |
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |
| | | | | | Not Applicable | Not Applicable | Not Applicable | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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Laboratory Data Hematology

| | | | |
|----|-----------------------------|--------------------------------|--------------------------|
| 1. | Lab Panel: | Not Applicable _____ | Comments |
| 2. | Laboratory Name and Address | Not Applicable _____ [] | Comments |
| 3. | Collection Date: | Not Applicable _____ // | Comments |
| 4. | Specimen Type: | Not Applicable _____ | Comments |

Lab Result

| | | | |
|-----|-------------|--|--------------------------|
| 5.a | Sponsor ID: | Not Applicable _____ [] | Comments |
| | Test: | Hemoglobin_PX1 | |
| | Result: | Not Applicable _____ [] | Comments |
| | Not Done: | Not Applicable _____ | Comments |
| | LNMT | Not Applicable _____ Low [] High [] Unit | Comments |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.b | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Hematocrit_PX2 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.c | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Erythrocytes_PX3 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.d | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Platelets_PX5 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.e | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Leukocytes_PX7 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5 f | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Neutrophils_PX608 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.g | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Eosinophils_PX609 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unsheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Nov/12/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.h | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Monocytes_PX612 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

| | | | |
|-----------|-----------------------------------|--------------------------|--------------------------|
| 5.i | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Basophils_PX610 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|-----|-------------|---|--------------------------|
| 5.j | Sponsor ID: | Not Applicable [] | Comments |
| | Test: | Lymphocytes_PX611 | |
| | Result: | Not Applicable [] | Comments |
| | Not Done: | Not Applicable | Comments |
| | LNMT | Not Applicable Low [] High [] Unit | Comments |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Date: | Vital Signs Details | | | Form Instance |
|----|----------------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Not Applicable | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |
| | | Not Applicable | Not Applicable | Not Applicable | |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

Header Text: c4591001
Visit: POT_COVID_ILL 1 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Form Version: 06-Jul-2020 21:55
Site No: 1097 **Site Name:** (1097) Main Street Physician's Care - Waterway
Subject No: 10971061 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:39

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|----------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1
Form: IMAGING
Form Version: 06-Jul-2020 21:53
Site No: 1097
Site Name: (1097) Main Street Physician's Care - Waterway
Subject No: 10971061
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:39

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Dec/11/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Dec/11/2020 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

| | | |
|----|-------------------------|----------|
| 3. | COVID-19 Illness Visit: | COVID_A1 |
|----|-------------------------|----------|

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Dec/11/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Dec/11/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BPVC70] |
| 5.b | Sample ID | [BPVC71] |
| 5.c | Sample ID | [BPVC72] |
| 5.d | Sample ID | [BL9XSF] |
| 5.e | Sample ID | [BL9XSG] |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Unplanned Assessments

| | | |
|----|-------------|--|
| 1. | Assessments | |
|----|-------------|--|

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Nov/12/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Disposition - Follow-Up

| | | |
|----|---|-----|
| 1. | Date of Completion/Discontinuation /Death : | // |
| 2. | Phase of Disposition: | |
| 3. | Status: | |
| 4. | Specify Status: | [] |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

COVID-19 Repeat Swab

| | | |
|----|-----------------------|--|
| 3. | COVID-19 Repeat Swab: | |
|----|-----------------------|--|

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Uremic encephalopathy] |
| 4. | Start Date Time: | Oct/22/2020 23:58 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Oct/25/2020 11:48 |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [uremic encephalopathy due to AKI.] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|--|----------------------------------|
| 11. | Was a Concomitant Medication given? | YES |
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED WITH SEQUELAE |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020426230] |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [2] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Acute kidney injury] |
| 4. | Start Date Time: | Oct/22/2020 23:57 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Oct/25/2020 11:48 |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: CONCOMITANT DRUG TREATMENT |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 11. | Was a Concomitant Medication given? | YES |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | |
|-----|--|----------------------------------|
| 12. | Was a Non-Drug Treatment given? | NO |
| 13. | What was the outcome of this adverse event?: | RECOVERED/RESOLVED WITH SEQUELAE |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020426230] |

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category | Medication Error | Start Date | Is the medication error Still Ongoing | Study Medication Errors Action | Form Instance |
|----|----------|------------------|------------|---------------------------------------|--------------------------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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Medication Error

| | | |
|-----|---|-----|
| 1. | Category: | |
| 2. | Medication Error (Type of Medication Error): | [] |
| 3. | Start Date: | // |
| 4. | Is the medication error still ongoing? | |
| 5. | Latest Action Taken with Study Treatment: | |
| 6. | Was a Concomitant Medication given? | |
| 7. | Was a Non-Drug Treatment given? | |
| 8. | Did the Medication Error cause the subject to be discontinued from the study? | |
| 9. | Was this medication error associated with any adverse events? | |
| 10. | Serious Adverse Event Number: For Pfizer Use Only | [] |

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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Concomitant Medications

| | | |
|----|---|-----|
| 1. | What is the medication identifier? | [] |
| 2. | Category: | |
| 3. | Concomitant Medications Pre-specified: | |
| 4. | Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [] |
| 5. | Date: | // |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Dose Description | Form Instance |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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Concomitant Medications

| | | |
|-----|---|-----|
| 1. | What is the medication identifier? | [] |
| 2. | Category: | |
| 3. | Concomitant Medications Pre-specified: | |
| 4. | Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | [] |
| 5. | Dose: | [] |
| 6. | Dose Unit: | |
| 7. | Dose Frequency: | |
| 8. | Route: | |
| 9. | Start Date: | // |
| 10. | Ongoing? | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Category | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Start Date | Form Instance |
|----|----------|----------------------|---------------------------------------|-----------|------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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Radiation Treatment

| | | |
|----|---|-----|
| 1. | Category: | |
| 2. | What is the treatment Identifier? | [] |
| 3. | Concomitant Non-drug Treatment Pre-specified: | |
| 4. | Treatment: | [] |
| 5. | Start Date: | // |
| 6. | Ongoing? | |

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| # | Transfusion Type | Date of Transfusion | Form Instance |
|----|------------------|---------------------|---------------------------------|
| 1. | | | Repeating Pages |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| | | |
|----|----------------------|----|
| 1. | Transfusion Type: | |
| 2. | Date of Transfusion: | // |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Vital Signs

| | | |
|----|-------|----|
| 1. | Date: | // |
|----|-------|----|

Vital Signs Details

| | | |
|----|-----------------------|-----|
| 2. | Record Identifier: | |
| | Temperature: | [] |
| | Unit: | |
| | Temperature Location: | |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Lab Urinalysis

| | | |
|----|---------------------------------------|-----|
| 1. | Lab Panel: | |
| 2. | Lab Sub-Panel: | |
| 3. | Collection Date: | // |
| 4. | Laboratory Name and Address (Derived) | [] |
| 5. | Specimen Type: | |

Lab Result

| | | |
|----|-------------|-----|
| 6. | Sponsor ID: | [] |
| | Test: | |
| | Result: | |
| | Not Done: | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Vaccination

| | | |
|-----|---|-----|
| 1. | Was there a temporary delay of vaccination? | |
| 2. | Treatment Name | [] |
| 3. | Formulation: | |
| 4. | Dose Date Time: | // |
| 5. | Anatomical Location: | |
| 6. | Body Side: | |
| 7. | Route: | |
| 8. | Actual Dose: | [] |
| 9. | Unit: | |
| 10. | Timeframe Subject Was Observed | |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 1

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Contact Outcome

| | | |
|----|-------------------|-----|
| 1. | Contact Type: | |
| 2. | Was contact made? | |
| 3. | Comments: | [] |

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: CONTACT OUTCOME - MONTH 6

Form Version: 10-Oct-2020 16:01

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Contact Outcome

| | | |
|----|-------------------|-----|
| 1. | Contact Type: | |
| 2. | Was contact made? | |
| 3. | Comments: | [] |

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02 **Form Status:** Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date of Visit

| | | |
|----|-----------------|----|
| 1. | Date of Visit | // |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

Form Version: 14-Jan-2021 02:29

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Informed Consent - Asymptomatic Surveillance

| | | |
|----|--------------|--|
| 1. | Consent Was: | |
|----|--------------|--|

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V201_SURVEIL_CONSENT - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Electronic Sample Tracking

| | | |
|----|--|-----|
| 1. | Data Origin | |
| 2. | Sample Type | |
| 3. | Sample Collected? | |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|----|-----------|-----|
| 5. | Sample ID | [] |
|----|-----------|-----|

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/25/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

| | | |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Jan/25/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

090177e196ae3e3e3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Withdrawal Of Consent

| | | |
|----|------------------------------|----|
| 1. | Withdrawal of Consent Date : | // |
|----|------------------------------|----|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Death Details

| | | |
|----|---|----|
| 1. | Date of Collection / Notification of Death: | // |
|----|---|----|

Cause of Death

| | | |
|----|------------------------|-----|
| 2. | Cause of Death Status: | |
| | Cause of Death: | [] |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Nov/12/2020 |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

Casebook Signature Form

| | | |
|----|--------------------|----------------------|
| 1. | Casebook Signature | Click Here to Enable |
|----|--------------------|----------------------|

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|--|------------------|------------|
| Form | Aug-28-2020 15:57:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Incomplete |
| | | | Not Done |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|--|
| Form | Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | subject stated they had a hysterectomy |
| | | | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|--|
| 1 | Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | subject stated they had a hysterectomy |
| | | | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|--|
| 3 | Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | subject stated they had a hysterectomy |
| | | | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|--|
| 4 | Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | subject stated they had a hysterectomy |
| | | | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 5 | Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | <div data-bbox="964 407 1484 464">subject stated they had a hysterectomy</div> <hr/> <div data-bbox="964 464 1484 510">Not Applicable</div> |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|--|
| 6.a | Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | subject stated they had a hysterectomy |
| | | | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|--|
| 6.a | Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | subject stated they had a hysterectomy |
| | | | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|--|
| 6.a | Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | subject stated they had a hysterectomy |
| | | | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| 2 | Nov-24-2020 16:37:39 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Subject had no signs or symptoms of COVID Not Applicable |
| 2 | Nov-24-2020 12:08:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Subject had no signs or symptoms of COVID |
| 2 | Nov-23-2020 08:57:32 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | |
| 2 | Nov-19-2020 16:40:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 3 | Nov-20-2020 10:48:43 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - Comments

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|--------------------------------|----------------|
| 4.a | Nov-20-2020 10:49:08 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|------------------------|
| Form | Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| Form | Nov-24-2020 12:39:55 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | done |
| Form | Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |
| Form | Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| Form | Nov-24-2020 12:33:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | No test done for COVID |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| 3 | Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |
| 3 | Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| 3 | Nov-20-2020 10:50:49 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form: MICROBIOLOGY SPECIMEN - Comments**

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 4 | Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |
| 4 | Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |
| 4 | Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 5 | Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |
| 5 | Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |
| 5 | Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 6 | Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |
| 6 | Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |
| 6 | Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |
| 6 | Nov-17-2020 12:22:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 8 | Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| 8 | Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |
| 8 | Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| 8 | Nov-17-2020 12:21:22 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 9 | Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| 9 | Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |
| 9 | Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |
| 9 | Nov-19-2020 16:44:59 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|-----------------------|
| 3 | Nov-19-2020 16:37:46 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | sample was collected. |
| 3 | Nov-19-2020 16:37:25 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | sample was collected. |
| 3 | Nov-18-2020 09:41:01 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 2 | Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

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Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 4 | Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 5 | Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [redacted] | Not Applicable |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway


Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|-------------|---|---|----------------|
| 6 | Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6)  | Not Applicable |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Nov-25-2020 08:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | |
| Form | Nov-24-2020 15:12:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Nov-25-2020 08:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | |
| 1 | Nov-24-2020 15:12:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 2 | Nov-25-2020 08:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | |
| 2 | Nov-24-2020 15:12:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 06-Jul-2020 21:52

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ILLNESS DETAILS - Comments

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 3 | Nov-25-2020 08:28:27 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | |
| 3 | Nov-24-2020 15:12:53 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 1 | Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 2 | Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 3 | Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 4 | Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
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| Form | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 1 | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 2 | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 3 | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 4 | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 5.a | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 5.a | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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| Item | Date | User | Comment |
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| 5.a | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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| Item | Date | User | Comment |
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| 5.a | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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| Item | Date | User | Comment |
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| 5.b | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 5.b | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| Item | Date | User | Comment |
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| 5.b | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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| Item | Date | User | Comment |
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| 5.b | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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| 5.c | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| 5.c | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

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Site No: 1097

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| 5.c | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

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| 5.c | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

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| 5.d | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

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| 5.d | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

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| 5.e | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

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| 5 f | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

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| 5.g | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

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| 5.g | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

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| 5.g | Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

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| Form | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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| 1 | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

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| 2 | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

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| 3 | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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| 4 | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

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| 5.a | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

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| 5.c | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

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| 5.d | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

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| 5.d | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| 5.d | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| 5.d | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

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| 5.e | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| 5.e | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1097

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| 5.e | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1097

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| 5 f | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

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| 5 f | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1097

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| 5 f | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| 5 f | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

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| 5.g | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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| 5.g | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

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| 5.g | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

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| 5.g | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

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| 5 h | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

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Site No: 1097

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| 5 h | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1097

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| 5 h | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

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| 5 h | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1097

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| 5.i | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1097

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| 5.i | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1097

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| 5.i | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Frozen

Site No: 1097

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| 5.j | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Frozen

Site No: 1097

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| 5.j | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Frozen

Site No: 1097

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| 5.j | Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020
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Form Version: 21-Aug-2020 02:50
Form Status: Data Complete, Frozen
Site No: 1097
Site Name: (1097) Main Street Physician's Care - Waterway
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| Form | Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - COVID - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

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| 1 | Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Site No: 1097

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| 2.a | Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** VITAL SIGNS - COVID - Comments
Form Version: 21-Aug-2020 02:50 **Form Status:** Data Complete, Frozen
Site No: 1097 **Site Name:** (1097) Main Street Physician's Care - Waterway
Subject No: 10971061 **Subject Initials:** ---
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| 2.a | Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

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Form Status: Data Complete, Frozen

Site No: 1097

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| 2.a | Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** OXYGENATION PARAMETERS - Comments

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1097

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| 1 | Nov-24-2020 15:16:23 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020
Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

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| Form | Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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Form Status: Data Complete, Frozen

Site No: 1097

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090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2 | Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae3e3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 4 | Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Applicable |

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Comments
 Nov/12/2020
Form Version: 06-Jul-2020 21:53 **Form Status:** Data Complete, Frozen
Site No: 1097 **Site Name:** (1097) Main Street Physician's Care - Waterway
Subject No: 10971061 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| Form | Nov-24-2020 15:17:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 1 | Nov-24-2020 15:17:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) ██████████ | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2 | Nov-24-2020 15:17:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 3 | Nov-24-2020 15:17:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Applicable |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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This form requires signing by a member of each of the following signature groups:

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|-----------------|-------------------|---|------|--------|
| Tom Christensen | Approved | Feb-24-2021 19:06:19 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-22-2021 12:33:17 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Tom Christensen | Approved | Jan-27-2021 21:01:37 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Jan-26-2021 14:16:19 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|---|------|--------|
| Tom Christensen | Approved | Jan-25-2021 19:38:57 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|---|------|--------|

Header Text: c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**Affidavit:**

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Jan-25-2021 14:56:00 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|--|------|--------|
| Tom Christensen | Approved | Jan-20-2021 20:48:21 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|--|------|--------|

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-----------------|----------|--|------|--------|
| Tom Christensen | Approved | Nov-17-2020 16:38:06 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|-----------------|----------|--|------|--------|

Affidavit:

By my dated signature below, I, TomChristensen, verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that this electronic signature is to be the legally binding equivalent of my handwritten signature.

To this I do attest by supplying my user name and password and clicking the button marked Submit below.

| | | | | |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Nov-17-2020 12:02:32 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-28-2020 13:57:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 24 JUL 2020 | Initial Entry |

2. Select appropriate response - What cohort does the subject belong to?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Aug-28-2020 13:57:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--|---------------|
| Aug-28-2020 13:57:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: OBTAINED Date Written Consent Obtained Aug/28/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Aug-28-2020 13:57:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10971061 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Aug-28-2020 13:57:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6) 1953 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-28-2020 13:58:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-28-2020 13:58:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

5. Race: (Check X all that apply):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Aug-28-2020 13:58:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: WHITE | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|-----------------------------------|---|
| Sep-02-2020 08:50:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Closed | Response satisfies query |
| Sep-02-2020 08:24:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Answered | Randomization number and date have been entered correctly |
| Sep-01-2020 02:04:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Opened | IVRS Reconciliation: Randomization date and randomization number recorded at Impala but not recorded at Inform. Please review and update data as appropriate. Else, clarify. Thank you. |
| Aug-28-2020 15:56:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Aug/28/2020 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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I.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-03-2020 15:16:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Term: Peripheral Vascular Disease Start Date: Feb/18/2020 Ongoing: YES | Initial Entry |

I.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:16:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

I.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------------|-------------------|---|
| Nov-09-2020 16:04:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Charu Sabharwal (b) (4) | Query 2: Closed | Response satisfies query |
| Nov-09-2020 09:59:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | pulmonary Fibrosis added to medical history. |
| Nov-07-2020 08:15:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Charu Sabharwal (b) (4) | Query 2: Opened | As confirmed in the AE log, subject has a known medial condition of apical fibrosis. Please update MedHx accordingly. |
| Nov-06-2020 16:23:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-06-2020 10:39:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Added in history |
| Nov-06-2020 02:46:45 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical On review of SAE report for kidney |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form Version: 22-Apr-2020 21:03
Site No: 1097
Subject No: 10971061
Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1097) Main Street Physician's Care - Waterway
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|---|---|
| (US & Canada) | | (b) (4) | | injury, Medical Hx of HTN was mentioned, yet it does not appear in the CRF. Please review for clinical relevance to this safety event and update Med Hx log CRF if appropriate. |
| Nov-05-2020 10:58:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Candidate | Clinical On review of SAE report for kidney injury, Medical Hx of HTN was mentioned, yet it does not appear in the CRF. Please review for clinical relevance to this safety event and update Med Hx log CRF if appropriate. |
| Sep-03-2020 15:16:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Peripheral Vascular Disease | Initial Entry |

I.a Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:16:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/18/2020 | Initial Entry |

I.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:16:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-03-2020 15:17:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 2 Medical History Term: Chronic depression Start Date: Apr/22/2018 Ongoing: YES | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

I.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:17:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 2 | Initial Entry |

I.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--|---|
| Nov-12-2020 07:10:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkoyd (b) (4) | Query 1: Closed | Response satisfies query |
| Nov-11-2020 15:29:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | subject meets qualification . |
| Nov-10-2020 14:02:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkoyd (b) (4) | Query 1: Opened | GPD CLIN: The subject presents at screening with ongoing depression. Please confirm subject meets eligibility per exclusion criteria 1; else, document deviation on I/E CRF and report deviation as applicable. |
| Sep-03-2020 15:17:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Chronic depression | Initial Entry |

I.b Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:17:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Apr/22/2018 | Initial Entry |

I.b Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:17:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

I.c

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-03-2020 15:18:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number: 3 Medical History Term COPD : Start Date: Mar/23/2018 Ongoing: YES | Initial Entry |
| Sep-03-2020 15:17:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 3 Medical History Term COPD : Start Date: Mar/23/2018 Ongoing: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:17:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 3 | Initial Entry |

I.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|--------------------|---|
| Nov-06-2020 16:23:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Nov-06-2020 11:09:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | This was found on CT of the chest performed 22Oct2020. This was unknown prior to that time so it should not be added as history. |
| Nov-06-2020 04:07:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical On review of SAE report for kidney injury, Med Hx of pulmonary fibrosis was reported (with no start date). If this is a pre-existing condition, please add to Med Hx and submit start date to SAE. |
| Nov-05-2020 11:01:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Candidate | Clinical On review of SAE report for kidney injury, Med Hx of pulmonary fibrosis was reported (with no start date). If this is a pre-existing condition, please add to Med Hx and submit start date to SAE. |
| Sep-06-2020 08:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkoyd (b) (4) | Query 1: Closed | Response satisfies query |
| Sep-05-2020 14:50:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | The participant is not currently receiving or plans to receive systemic |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|--------------------------------|----------------------------|---|
| | | | | corticosteroids with the exception of Inhaled Steroids due to this condition. |
| Sep-04-2020 15:26:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkoyd (b) (4) | Query 1: Opened | GPD Clin: The subject presents at screening with ongoing COPD. Please confirm that participant is or is not currently receiving/plans to receive systemic corticosteroids with the exception of Inhaled Steroids due to this condition. |
| Sep-03-2020 15:17:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> COPD | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:17:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Mar/23/2018 | Initial Entry |

I.c Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:18:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-03-2020 15:18:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number: 4 Medical History Term: Fibromyalgia Start Date: Mar/23/2018 Ongoing: YES | Initial Entry |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

I.d Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:18:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

I.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Sep-03-2020 15:18:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Fibromyalgia | Initial Entry |

I.d Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:18:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/23/2018 | Initial Entry |

I.d Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:18:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.e

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-03-2020 15:19:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: r: Medical History Degenerative Lumbar disc Term: Start Date: Mar/23/2018 Ongoing: YES | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

I.e Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:19:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 5 | Initial Entry |

I.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-03-2020 15:19:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Degenerative Lumbar disc | Initial Entry |

I.e Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:19:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/23/2018 | Initial Entry |

I.e Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:19:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-03-2020 15:20:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number: 6 Medical History Term: Vit D deficiency Start Date: Mar/23/2018 Ongoing: YES | Initial Entry |
| Sep-03-2020 15:20:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 6 Medical History Term: Vit D deficiency Start Date: Mar/23/2018 Ongoing: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

I.f Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:20:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

I.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-03-2020 15:20:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Vit D deficiency | Initial Entry |

I.f Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:20:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/23/2018 | Initial Entry |

I.f Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:20:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-03-2020 15:21:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 7 Medical History Term: ADHD Start Date: Mar/23/2018 Ongoing: YES | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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I.g Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:21:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

I.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-03-2020 15:21:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ADHD | Initial Entry |

I.g Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:21:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/23/2018 | Initial Entry |

I.g Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:21:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.h

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-03-2020 15:21:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 8 Medical History Term: Anxiety Start Date: Mar/23/2020 Ongoing: YES | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

I.h Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:21:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 8 | Initial Entry |

I.h Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Sep-03-2020 15:21:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Anxiety | Initial Entry |

I.h Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:21:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/23/2020 | Initial Entry |

I.h Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:21:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.i

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-03-2020 15:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 9 Medical History Term: Hyperlipidemia Start Date: Mar/23/2018 Ongoing: YES | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

I.i Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-03-2020 15:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 9 | Initial Entry |

I.i Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-03-2020 15:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Hyperlipidemia | Initial Entry |

I.i Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-03-2020 15:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/23/2018 | Initial Entry |

I.i Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-03-2020 15:22:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.j

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Nov-06-2020 10:38:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 10 Medical History Term: Hypertension Start Date: Mar/23/2018 Ongoing: YES | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

I.j Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Nov-06-2020 10:38:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10 | Initial Entry |

I.j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------------|---------------|
| Nov-06-2020 10:38:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Hypertension | Initial Entry |

I.j Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Nov-06-2020 10:38:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/23/2018 | Initial Entry |

I.j Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Nov-06-2020 10:38:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.k

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Nov-09-2020 09:56:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 11 Medical History Term: Pulmonary Fibrosis Start Date: Dec/UNK/2015 Ongoing: YES | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

1.k Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Nov-09-2020 09:56:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11 | Initial Entry |

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-09-2020 09:56:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Pulmonary Fibrosis | Initial Entry |

1.k Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Nov-09-2020 09:56:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/UNK/2015 | Initial Entry |

1.k Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-09-2020 09:56:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/28/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 135.0 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LB | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 65.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: in | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 22.5 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location:: ORAL CAVITY | Initial Entry |
|---|-----------------|---------------------|---|---------------|

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.5 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-28-2020 15:58:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form Version:** 21-Aug-2020 02:49**Site No:** 1097**Subject No:** 10971061**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Lab Panel:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|------------------|----------------|
| | | | Result: | Not Applicable |
| | | | Not Done: | Not Applicable |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Sep-02-2020 08:18:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-03-2020 15:24:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-03-2020 15:24:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Sep-03-2020 15:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-03-2020 15:24:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-03-2020 15:24:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/28/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-03-2020 15:24:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN69ZV | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 15:24:33 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BN69ZV | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|---------------|--|------------------|--|
| (US & Canada) | | (b) (4), (b) (6) | |
|---------------|--|------------------|--|

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-03-2020 15:24:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BN69ZS | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 15:24:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN69ZS | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-03-2020 15:25:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BN69ZT | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 15:25:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN69ZT | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1097
Site Name: (1097) Main Street Physician's Care - Waterway
Subject No: 10971061
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-03-2020 15:25:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-03-2020 15:25:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Sep-03-2020 15:26:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-03-2020 15:25:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-03-2020 15:25:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/28/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-03-2020 15:26:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BN6BDC | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Sep-03-2020 15:26:18 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BN6BDC | Initial Entry |

Header Text: c4591001
Visit: V1_DAY1_VAX1_L
Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
Form Version: 22-Apr-2020 21:03
Form Status: Data Complete, Locked, Frozen, Verified
Site No: 1097
Site Name: (1097) Main Street Physician's Care - Waterway
Subject No: 10971061
Subject Initials: ---
Generated By: (b) (4)
Generated Time (GMT): 29-Mar-2021 10:39

| | |
|---------------|------------------|
| (US & Canada) | (b) (4), (b) (6) |
|---------------|------------------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/28/2020 13:35 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |
|---|-----------------|-------------------------|-------------------------------------|---------------|

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-02-2020 08:20:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-28-2020 15:59:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES - REACTOGENICITY E-DIAR Y COLLECTED FOR THIS SUBJEC T | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Sep-22-2020 14:23:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/17/2020 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> FE VE R <u>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</u> NO | Initial Entry |

2.a Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> FEVER | Initial Entry |

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> <u>Symptom::</u> FAT IG UE | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|--|--|--|---|--|
| | | | Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | |
|--|--|--|---|--|

2.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.d

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: CH ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: VO MIT ING Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: DIA RR HE A Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---------------|--|--|---|--|
| (US & Canada) | | | Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?: | |
|---------------|--|--|---|--|

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENERED MUSCLE P AIN | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.h

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Symptom:: NEW OR WORSEN ED JOIN T PAIN Were fever or systemic NO symptoms present on t he last day the Subject Diary was completed?: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENERD JOINT PAI N | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|----------------------------|--|
| Sep-23-2020 14:31:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Sep-23-2020 10:14:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Answer Auto Query |
| Sep-23-2020 10:14:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | So it will be changed to the arm used at Visit 1. |
| Sep-23-2020 05:08:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM: Please review the injection site on vaccination page of V1D1VX1L is reported as Left however for the symptoms diary here its is recorded as right which seems incorrect. Please review and update as |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|-----------------------------|--|
| | | | | appropriate. |
| Sep-22-2020 14:29:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Injection could not be given in the left deltoid due to the presence of a Fentanyl Patch on the left arm. |
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Injection Site Body Side entered on this page is not matching with Body Side entered on Vaccination page of VIDIVX1L. Please review and update as appropriate. |
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction: RE DN ESS Were injection site reactions NO present on the last day the S ubject Diary was completed? : | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: REDNESS | Initial Entry |

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: SWE LLI NG Were injection site reactions NO present on the last day the S ubject Diary was completed ?: | Initial Entry |

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: PAIN A T INJEC TION SI TE Were injection site reacti NO ons present on the last d ay the Subject Diary was completed?: | Initial Entry |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

5.c Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:28:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** V2_VAX2_L**Form Version:** 15-Sep-2020 21:54**Site No:** 1097**Subject No:** 10971061**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Sep-22-2020 14:30:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/17/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-22-2020 14:30:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: ORAL CAVITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-22-2020 14:30:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Sep-22-2020 14:30:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.9 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Sep-22-2020 14:30:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Sep-22-2020 14:30:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/17/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 Result:: | Initial Entry |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | | |
|--|--|--|------------|----------|--|
| | | | Not Done:: | NOT DONE | |
|--|--|--|------------|----------|--|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Sep-22-2020 14:31:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NOT DONE | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-22-2020 14:31:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-22-2020 14:31:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Sep-23-2020 10:16:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-23-2020 06:05:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-22-2020 14:31:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-22-2020 14:31:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/17/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------|---------------|
| Sep-23-2020 10:16:13 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---------------|--|--|--------------------------|--|
| (US & Canada) | | | Sample ID: BN6B4B | |
|---------------|--|--|--------------------------|--|

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Sep-23-2020 10:16:13 (UTC-05:00) Eastern Time (US & Canada) | ACVOPFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BN6B4B | Initial Entry |

Header Text: c4591001
Visit: V2_VAX2_L
Form Version: 22-Apr-2020 21:04
Site No: 1097
Subject No: 10971061
Generated By: (b) (4)
Form: VACCINATION - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen, Verified
Site Name: (1097) Main Street Physician's Care - Waterway
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:39

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/17/2020 14:03 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Initial Entry |

7. Route:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |
|---|-----------------|-------------------------|-------------------------------------|---------------|

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Sep-22-2020 14:32:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|---|-------------------------|---|--|
| Nov-18-2020 11:13:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Clo sed | Response satisfies query |
| Nov-18-2020 09:22:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Ans wered | PATIENT WAS IN HOSPITAL AND THEN WENT TO STAY WITH HER DAUGHTER FOR A SHORT TIME. WE KEPT IN TOUCH WITH HER AND GOT HER IN AS QUICKLY AS POSSIBLE. |
| Nov-18-2020 03:46:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD (b) (4) | Query 1: Op ened | PDQ: Date of visit at V3_MONTH1_POSTVAX2_L is out of window for 21 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately. (b) (4) |
| Nov-16-2020 13:33:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Nov/1 2/202 0 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001
Visit: V3_MONTH1_POSTVAX2_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History
Form Version: 21-Aug-2020 02:52 **Form Status:** Data Complete, Locked, Frozen, Verified
Site No: 1097 **Site Name:** (1097) Main Street Physician's Care - Waterway
Subject No: 10971061 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:39

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I. Were medications to treat fever/pain given on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---|
| Nov-18-2020 11:14:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-18-2020 09:23:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | COMPLETED |
| Nov-18-2020 00:24:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Please complete rest of the fields on this form. Thank you. |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FE VE R Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Initial Entry |

2.a Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FAT IGU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: FAT IGU E Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Initial Entry |

2.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FATIGUE | Initial Entry |

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: HEA DAC | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|--|---------------|
| | | | HE NO Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: HEA DAC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Initial Entry |

2.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HEADACHE | Initial Entry |

2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: CH ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: CH ILL S Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Initial Entry |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: VO MITI NG Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: DIA RRH EA Were fever or systemic symptoms present on the last day the Subject Diary was completed?: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic s NO ymptoms present on the last day the Subject Dia ry was completed?: | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSEN ED MUSC LE PAIN Were fever or systemic s ymptoms present on the last day the Subject Dia ry was completed?: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.g Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENER MUSCLE PAI N | Initial Entry |

2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSENER ED JOINT PAIN Were fever or systemic s NO ymptoms present on the last day the Subject Diar y was completed?: | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: NEW OR WORSENER ED JOINT PAIN Were fever or systemic s ymptoms present on the last day the Subject Diar y was completed?: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR WORSENERD JOINT PAIN | Initial Entry |

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Injection Site Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

4. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------|--|
| Nov-18-2020 09:22:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Nov-18-2020 09:22:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RIGHT | Transcription Error |
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Injection Site Body Side entered on this page is not matching with Body Side entered on Vaccination page of V2VX2L. Please review and update as appropriate. |
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions p resent on the last day the Subj ect Diary was completed?: NO | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: RE DN ESS Were injection site reactions p resent on the last day the Subj ect Diary was completed?: | Initial Entry |

5.a Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: REDNESS | Initial Entry |

5.a Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: SWE LLIN G Were injection site reactions p resent on the last day the Subj ect Diary was completed?: NO | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: SWE LLIN G | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|---|--|
| | | | Were injection site reactions present on the last day the Subject Diary was completed?: | |
|--|--|--|---|--|

5.b Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWELLING | Initial Entry |

5.b Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: NO | Initial Entry |
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Injection Site Reaction:: PAIN AT INJECTION SITE Were injection site reactions present on the last day the Subject Diary was completed?: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.c Injection Site Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-16-2020 13:34:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PAIN AT INJECTION SITE | Initial Entry |

5.c Were injection site reactions present on the last day the Subject Diary was completed?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-18-2020 09:20:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-16-2020 13:38:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-16-2020 13:38:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Nov-16-2020 13:38:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-16-2020 13:38:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-16-2020 13:38:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES Date of Collection: Nov/12/2020 | Initial Entry |

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------|---------------|
| Nov-17-2020 12:13:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------|---------------|
| Nov-16-2020 13:38:35 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Initial Entry |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---------------|--|------------------|-------------------|--|
| (US & Canada) | | (b) (4), (b) (6) | Sample ID: BPVCPH | |
|---------------|--|------------------|-------------------|--|

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-16-2020 13:38:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPVCPH | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-16-2020 13:38:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPVCPJ | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-16-2020 13:38:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPVCPJ | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-16-2020 13:39:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPVCPK | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-16-2020 13:39:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BPVCPK | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------------|
| Nov-17-2020 12:02:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BL9XR7 | Transcription Error |
| Nov-16-2020 13:40:36 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BL9XR8 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

(US & Canada)

(b) (4), (b) (6)

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|---|---------------------------|------------------------------|---|
| Nov-17-2020 15:13:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-17-2020 12:02:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-17-2020 12:02:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BL9XR7 | Transcription Error |
| Nov-16-2020 22:05:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW5391390;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate. |
| Nov-16-2020 13:40:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BL9XR8 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-16-2020 13:40:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BL9XR8 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|---|----------------------|------------------------------|---|
| Nov-17-2020 15:13:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-17-2020 12:03:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | BL9XR8 is correct. |
| Nov-16-2020 22:05:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW5391391;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate. |
| Nov-16-2020 13:40:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BL9XR8 | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Feb-22-2021 12:33:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BL9XR9 | Initial Entry |

5.f Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Feb-22-2021 12:33:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BL9XR9 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------------|--|
| Nov-20-2020 10:44:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Nov-20-2020 03:28:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Nov-17-2020 12:14:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate. |
| Nov-17-2020 12:14:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Nov-17-2020 12:14:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/12/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------|---------------|
| Nov-17-2020 12:14:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Assessment:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/12/2020 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---|
| Nov-25-2020 05:05:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-24-2020 16:37:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-24-2020 15:43:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Should this be an erroneous visit since subject was asymptomatic |
| Nov-23-2020 08:57:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Nov-23-2020 00:01:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM : COV ILL visit is not marked as Erroneous visit. However, Not Applicable is recorded on SOD CRF. Please review and update. Else, clarify. |
| Nov-20-2020 10:50:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | No symptoms. |
| Nov-19-2020 16:40:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-18-2020 05:06:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Kindly review the form and update. |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 10:48:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-20-2020 10:49:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: Not Applicable | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

4.a Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-20-2020 10:49:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASE D COUGH Symptom Present: NO | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASE D COUGH | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|------------------|--|
| | | | Symptom Present: | |
|--|--|--|------------------|--|

4.b Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom NEW OR INCREASED S s: HORTNESS OF BREATH Symptom NO Present: | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptom NEW OR INCREASED S s: HORTNESS OF BREATH Symptom Present: | Initial Entry |

4.c Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

4.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: NO | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: | Initial Entry |

4.d Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P NO resent: | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN Symptom P resent: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.e Symptoms:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: | Initial Entry |

4.f Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: NO | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: | Initial Entry |

4.g Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SORE THRO AT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARRHEA Symptom Present: NO | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARRHEA Symptom Present: | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

4.h Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMITING Symptom Present: NO | Initial Entry |
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMITING Symptom Present: | Initial Entry |

4.i Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-17-2020 12:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-23-2020 08:56:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Actual Date of Collection:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-17-2020 12:21:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---|
| Nov-25-2020 23:48:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-25-2020 08:19:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Form level comment changed to not done. |
| Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-25-2020 03:54:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM2: Please add new form level as 'Not Applicable' comment. Please Refer to section 4.11.3/4.10 of completion guidelines. Contact CRA if needed. Thank you. |
| Nov-24-2020 12:40:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|--------------------------------|--------------------------------------|--|
| Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Not Applicable | Initial Entry |
| Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Not Done | Initial Entry |
| Nov-23-2020 00:29:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Query 1: Reissued:Opened | DM1: Please add new form level 'Not Applicable' comment instead of item level. Refer to section 4.11.3/4.10 of completion guidelines. Contact CRA if needed. |
| Nov-20-2020 10:51:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Query 1: Answered | not applicable |
| Nov-19-2020 16:43:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Not Applicable | Initial Entry |
| Nov-18-2020 05:06:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Query 1: Opened | DM: Kindly consider to update this form if require else mark as Not applicable by selecting form level comment. Thank you. |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------------------------------|---------------|
| Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Not Done | Initial Entry |
| Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Not Applicable | Initial Entry |
| Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Not Done | Initial Entry |
| Nov-20-2020 10:50:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-25-2020 08:17:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-24-2020 12:35:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Nov-24-2020 12:34:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Nov-17-2020 12:22:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

7. Test Result:

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-24-2020 12:36:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-24-2020 12:36:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------|---|
| Nov-26-2020 02:11:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-25-2020 08:27:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Answer Auto Query |
| Nov-25-2020 05:20:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM1: Kindly review and update the reason why sample is not collected under 'If no sample was collected or sample was not collected according to protocol, please provide reason' in this CRF. Thank you |
| Nov-24-2020 12:38:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | no self swab collected |
| Nov-24-2020 12:36:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | 'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|--------------------------|--|
| | | | | is missing. Please review and update as appropriate. |
| Nov-24-2020 12:36:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-25-2020 08:27:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Patient was in hospital then went to stay with her daughter. We were unable to make contact with her for a brief period of time. | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-20-2020 10:44:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Nov-20-2020 10:44:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------|---|
| Nov-25-2020 06:27:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Nov-24-2020 12:39:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | no self swab |
| Nov-24-2020 12:31:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Closed | Close Auto Query |
| Nov-24-2020 12:31:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | There are more than 1 barcode present for sample collection. Please review and correct as appropriate. |
| Nov-24-2020 02:42:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | DM: Date of Visit is completed but 'Nasal Self Swab' CRF is not initiated. Please review and update the Nasal Self Swab data as |

090177e196ae3e3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|---|------------------------------------|---|--|
| | | | | appropriate. Thanks |
| Nov-23-2020 00:46:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Closed | Response satisfies query |
| Nov-20-2020 10:44:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Nov-20-2020 10:44:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry : YES Date of Collection: Nov/12/2020 | Initial Entry |
| Nov-20-2020 02:30:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Re issued: Opened | DM: Sample is collected please update rest of the details on this form. Thank you. |
| Nov-19-2020 16:37:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry : | Initial Entry |
| Nov-19-2020 16:31:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Answered | sample done |
| Nov-19-2020 02:10:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) [REDACTED] | Query 1: Opened | DMW5416031; Sample Collected is not expected to be Not Done. Please review and update appropriately or clarify |
| Nov-18-2020 09:41:01 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry : Not Done | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

(US & Canada)

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:35:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPVCPF | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-19-2020 16:35:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPVCPF | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------------|
| Nov-24-2020 12:31:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: | Transcription Error |
| Nov-24-2020 12:31:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPVCPF | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------------|
| Nov-24-2020 12:31:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |
| Nov-24-2020 12:31:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPVCPF | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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I.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO | Initial Entry |

I.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

I.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES Number of Visits or Contacts: 1 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39***I.b Physician or Healthcare Professional:***

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROOM | Initial Entry |

I.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

I.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

I.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

I.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

I.d

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | Initial Entry |

1.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

1.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO | Initial Entry |

1.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: TELEPHONE CONSULTATION | Initial Entry |

1.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-19-2020 16:29:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.f

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. What is the treatment Identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Concomitant Non-drug Treatment Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Nov-25-2020 08:29:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: POTENTIAL COVID-19 ILLNESS | Initial Entry |
| Nov-25-2020 08:28:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Nov-24-2020 15:12:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Was a diagnosis obtained for Potential COVID-19 Illness?

| Date | Location | User | Value | Reason |
|---|---|---------------------------|--------------------------|---|
| Nov-25-2020 15:33:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Closed | Auto closed by Validation Check: VC_CEIDT008_01 |
| Nov-25-2020 08:29:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Nov-25-2020 08:29:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
| Nov-25-2020 08:28:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Nov-25-2020 04:41:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW6235942; Was a diagnosis obtained for Potential COVID-19 Illness? is not expected to be Unknown or Not |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|--------------------------------|--------------------------------------|---|
| | | | | Applicable. Please review and update appropriately or clarify |
| Nov-24-2020 15:12:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Not Applicable | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|---|--------------------------------|--|--|
| Nov-25-2020 15:33:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Closed | Auto closed by Validation Check: VC_CEIDT008_03 |
| Nov-25-2020 08:29:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Nov-25-2020 08:29:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry : 0 | Initial Entry |
| Nov-25-2020 08:28:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry : | Initial Entry |
| Nov-25-2020 04:41:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW6236000;Toxicity Grade is not expected to be Not Done or Not Applicable or Unknown. Please review and update appropriately or clarify |
| Nov-24-2020 15:12:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry : Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Subcategory of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Was a diagnosis obtained?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:13:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

090177e196ae3e3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifi Not Applica | Initial Entry |

090177e196ae3e3e\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|--|--|--|---|
| | | | fier: ble Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable |
|--|--|--|---|

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifi Not Applica | Initial Entry |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|--|--|--|---|
| | | | fier: ble Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable |
|--|--|--|---|

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form Version: 21-Aug-2020 02:49

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:14:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3e3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|-------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identity Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|--|--|--|---|
| | | | fier: ble Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable |
|--|--|--|---|

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | | |
|--|--|--|--------------------------|----------------|--|
| | | | Not Done:: | Not Applicable | |
| | | | Lab Normal Range: | Not Applicable | |

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Sponsor-Defined Identifier</u> Not Applicable | Initial Entry |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | | |
|--|--|--|--------------------------|----------------|--|
| | | | fier: | ble | |
| | | | Test:: | Not Applicable | |
| | | | Result:: | Not Applicable | |
| | | | Not Done:: | Not Applicable | |
| | | | Lab Normal Range: | Not Applicable | |

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifi Not Applica | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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|--|--|--|--------------------------|----------------|--|
| | | | fier: | ble | |
| | | | Test:: | Not Applicable | |
| | | | Result:: | Not Applicable | |
| | | | Not Done:: | Not Applicable | |
| | | | Lab Normal Range: | Not Applicable | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Generated By: (b) (4)

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5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Result:: | Not Applicable |
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Not Appli cable Systolic:: Not Appli cable Diastolic:: Not Appli cable Respiratory Rate in respir ations/minute: Not Appli cable Heart Rate in beats/minut e: Not Appli cable | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a Diastolic:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:15:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-24-2020 15:16:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Not Applicable Oxygen Saturation: Not Applicable | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Date Time of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Arterial Blood Gases PaO2 (mmHg):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. FiO2 (Fraction of Inhaled Oxygen):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. What is the medication identifier?**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:16:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Nov/12/2020 Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:17:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:17:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Type of Imaging Exam:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:17:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Nov-24-2020 15:17:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail on Dec/11/2020 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|-----------------------------------|---------------|
| Dec-11-2020 12:52:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [redacted] | Data Entry: Dec/11/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------------------------|---------------|
| Dec-11-2020 12:52:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [redacted] | Data Entry: COVID_AI | Initial Entry |

090177e196ae3e3be\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit
on Dec/11/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971061**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-11-2020 12:53:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Dec-11-2020 12:53:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|---|--|
| Dec-11-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-11-2020 12:53:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Dec-11-2020 12:53:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: YES Date of Collection: Dec/11/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--|---------------|
| Dec-11-2020 12:54:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Sample ID: BPVC70 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------------|------------------------------|---------------|
| Dec-11-2020 12:54:31 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: BPVC70 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Dec/11/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | |
|---------------|--|------------------|--|
| (US & Canada) | | (b) (4), (b) (6) | |
|---------------|--|------------------|--|

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Dec-11-2020 12:54:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPVC71 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-11-2020 12:54:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPVC71 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Dec-11-2020 12:55:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPVC72 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-11-2020 12:55:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPVC72 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Dec-11-2020 12:55:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BL9XSF | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-11-2020 12:55:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BL9XSF | Initial Entry |

5.e

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|--|
| |
|--|

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Dec/11/2020 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--|---------------|
| Dec-11-2020 12:55:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: Sample ID: BL9XSG | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|------------------------------|---------------|
| Dec-11-2020 12:55:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: BL9XSG | Initial Entry |

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020 16:36:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/12/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-16-2020 16:36:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Nov-16-2020 16:36:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------|--------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|---|--------------------------------|---|---------------------------------|
| Nov-07-2020 08:51:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 5: Closed | Response satisfies query |
| Nov-06-2020 12:51:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 4: Closed | Discrepancy has been closed. |
| Nov-06-2020 11:17:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 5: Answered | Transcription Error |
| Nov-06-2020 11:17:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Answered | Transcription Error |
| Nov-06-2020 11:17:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Uremic encephalopathy | Transcription Error |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|---|---------------------------------|--|--|
| Nov-06-2020 09:50:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 3: Closed | Terms should be split and Acute Kidney Injury should be entered in a separate line, however there is a query from SAE RECON asking the site for the actions, thus to avoid duplicated requests this query is closed. |
| Nov-05-2020 22:11:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Opened | SAE RECON: AER#2020426230, Per narrative of the case, subject experienced Acute Kidney Injury which resulted to hospitalization. Please consider to split term and submit Acute Kidney injury as separate SAE in AE CRF. |
| Nov-05-2020 21:44:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 4: Opened | Special Characters: Verbatim Term contains embedded non-compliant characters. |
| Nov-05-2020 16:38:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | New Information |
| Nov-05-2020 16:38:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Deleted | New Information |
| Nov-05-2020 16:38:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: uremic encephalopathy Acute kidney injury | New Information |
| Nov-05-2020 15:27:19 (UTC-05:00) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 3: Opened | GPD Clin: Thanks for confirming the reason of uremic |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|--|-----------------|------------------------------|------------------------------|--|
| Eastern Time (US & Canada) | | | | encephalopathy was Acute Kidney Injury. Please enter it as a separate AE term, indicating it was a reason for hospitalization per information in safety database and previous query response, else clarify |
| Nov-05-2020 04:50:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued: Candidate | pending Clinical review |
| Nov-04-2020 15:10:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 1: Closed | updated query will be issued upon clarification with safety group |
| Nov-04-2020 10:12:07 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Uremic encephalopathy with acute kidney injury. |
| Nov-04-2020 10:11:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Uremic encephalopathy with acute kidney injury. |
| Nov-04-2020 05:52:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON: AER#2020426230, the term was reported as 'Acute kidney injury' in Safety database while recorded as 'uremic encephalopathy' in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form. |
| Nov-03-2020 13:27:33 (UTC-05:00) | ACV0PFEINFP6000 | Svitlana Tonkovyd (b) (4) | Query 1: Opened | GPD Clin: Can you please confirm the reason for chronic |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|---|--|
| Eastern Time (US & Canada) | | | | kidney disease that caused uremic encephalopathy, if known (examples: polycystic kidney disease, Diabetes mellitus, hypertension). Thanks. |
| Nov-03-2020 10:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: uremic encephalopathy | New Information |
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Altered Mental Status | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/22/2020 23:58 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|--|
| Nov-11-2020 21:25:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-11-2020 15:23:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-11-2020 15:23:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Oct/25/2020 11:48 | Transcription Error |
| Nov-11-2020 01:54:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINICAL - End date for Uremic encephalopathy is reported as 24Oct20; however, end date in SAE report for this |

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|---|--|
| | | | | event is 25Oct20. Please review to harmonize reporting, and update in the appropriate location. |
| Nov-10-2020 11:13:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Candidate | CLINICAL - End date for Uremic encephalopathy is reported as 24Oct20; however, end date in SAE report for this event is 25Oct20. Please review to harmonize reporting, and update in the appropriate location. |
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO End Date Time: Oct/24/2020 11:48 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 3 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------|---|
| Nov-11-2020 21:24:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 7: Closed | Query closed; will follow for SAE update with the requested COVID test info |
| Nov-11-2020 15:34:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 7: Answered | Form will be sent. The patient was not tested for COVID. |
| Nov-10-2020 11:18:33 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 7: Opened | CLINICAL Per a request by the |

Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

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| | | | | |
|---|-----------------|----------------------------|---|--|
| (US & Canada) | | | | independent Data Monitoring Committee, please submit a follow-up SAE form [#2020426230] to provide whether a COVID test was performed (YES/NO) in Hosp and if yes, the date/results. |
| Nov-07-2020 08:13:41 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Charu Sabharwal (b) (4) | Query 6: Closed | This needs to be updated in the medical history and will issue query in Med Hx CRF |
| Nov-07-2020 08:11:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Charu Sabharwal (b) (4) | Query 5: Closed | Will confirm if fu safety form has been submitted with the COVID testing update. |
| Nov-06-2020 08:06:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Answered | This is a pre-existing condition. |
| Nov-05-2020 19:12:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 6: Opened | CLINICAL - SAE report states subject has bilateral apical fibrosis on chest CT; please clarify if a known pre-existing condition and add to Med Hx, or if newly diagnosed, consider as a safety event for potential AE reporting |
| Nov-05-2020 19:02:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | Response satisfies query |
| Nov-05-2020 16:37:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 5: Answered | Changed Information |
| Nov-05-2020 16:37:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Answered | Changed Information |
| Nov-05-2020 16:37:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated wit | Changed Information |

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Form Status: Data Complete, Locked, Frozen

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| | | | | |
|---|-----------------|------------------|---|---|
| | | | <p>h congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p> | |
| Nov-05-2020 11:06:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 5: Opened | Clinical - COVID test status (yes/no) during Hospitalization has not been reported in the SAE submitted to safety. Please submit a follow-up SAE form [#2020426230] to provide whether COVID testing was performed and if yes, the results. |
| Nov-05-2020 11:04:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | CLINICAL - Reason for SAE status is both Hosp and Medically important; however, SAE report has only Hosp. Please review and harmonize between reports (2 |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|--------------------|---|
| | | | | reasons is acceptable). |
| Nov-04-2020 05:51:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Nov-04-2020 05:50:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Deleted | Close Auto Query |
| Nov-03-2020 10:31:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Candidate | For AE uremic encephalopathy: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Nov-03-2020 10:30:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Uremic encephalopathy |
| Nov-03-2020 08:26:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON: Altered Mental Status(Onset date:28Aug2020) is not reported to Safety database but marked serious on AE CRF. Confirm seriousness and report to Pfizer immediately. If this event is not serious, downgrade the event on AE CRF |
| Nov-03-2020 08:26:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Deleted | Query can be addressed internally |
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Altered Mental Status: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |

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Generated By: (b) (4)

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Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

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7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p> | Initial Entry |

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------------|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> <p>NO</p> | Initial Entry |

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Header Text: c4591001

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Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Nov-11-2020 21:21:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Nov-11-2020 15:30:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | added data. |
| Nov-11-2020 15:30:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER <i>If Other, specify:</i> uremic encaphalopathy due to AKI. | added data. |
| Nov-11-2020 01:57:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | CLINICAL - Uremic encephalopathy event is reported as related to the same event; however, the SAE event term is 'Uremic encephalopathy due to AKI'. Please review and update as appropriate. |
| Nov-10-2020 11:12:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Candidate | CLINICAL - Uremic encephalopathy event is reported as related to the same event; however, the SAE event term is 'Uremic encephalopathy due to AKI'. Please review and update as appropriate. |
| Nov-04-2020 03:24:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-03-2020 10:33:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |

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Header Text: c4591001

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Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|--------------------------------|--|---|
| Nov-03-2020 10:33:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: uremic encephalopathy | New Information |
| Nov-03-2020 00:42:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Query 1: Opened | DM: The response for "Is this event related to study treatment" Is reported as 'Not Related', however response for, 'Please indicate what this event is due to' is missing. Kindly review and update. |
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: NOT RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------------------------------|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|---------------------------|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|--------------------------|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: NO | Initial Entry |

13. What was the outcome of this adverse event?:

| | | | | |
|--|--|--|--|--|
| | | | | |
|--|--|--|--|--|

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Nov-05-2020 22:59:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-05-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Nov-05-2020 16:39:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED WITH SEQUELAE | Changed Information |
| Nov-05-2020 04:54:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | SAE RECON:AER#2020426230,outcome was reported as RECOVERED/RESOLVED WITH SEQUELAE to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form. |
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-02-2020 09:30:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Nov-04-2020 05:50:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020426230 | Initial Entry |

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Subject No: 10971061

Generated By: (b) (4)

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------|---|
| Nov-09-2020 12:56:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Nov-09-2020 10:04:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | not new added to medial history |
| Nov-08-2020 20:16:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | reworded |
| Nov-08-2020 20:05:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Clinical - if not pre-existing, the event pulmonary fibrosis should be reported as a new adverse event |
| Nov-08-2020 19:36:21 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | It is on the AE Log so it is reported. What are you asking? |
| Nov-06-2020 16:25:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clinical On review of SAE report for kidney injury, pulmonary fibrosis was reported and this has been clarified as NOT pre-existing. Please review for safety |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|---|---|
| | | | | impact, and if appropriate, report as an AE |
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Acute kidney injury | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Nov-08-2020 20:14:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | AE and SAE both have start date now of 22Oct20 |
| Nov-08-2020 19:36:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-08-2020 19:36:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/22/2020 23:57 | Transcription Error |
| Nov-07-2020 09:03:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | SAE RECON: AER#2020426230 onset date was reported as 22Oct2020 in Safety database however, recorded as 20Oct2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form. |
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/20/2020 23:57 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-------------------|--------------------------|
| Nov-11-2020 21:26:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-11-2020 15:35:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1097**Subject No:** 10971061**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|---|--|
| Nov-11-2020 15:35:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Oct/25/2020 11:48 | Transcription Error |
| Nov-10-2020 11:14:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINICAL - End date for Acute Kidney Injury is reported as 24Oct20; however, end date in SAE report for this event is 25Oct20. Please review to harmonize reporting, and update in the appropriate location. |
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Oct/24/2020 11:48 | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---------------------|
| Nov-07-2020 08:54:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Nov-06-2020 11:23:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Nov-06-2020 11:23:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated wit | Transcription Error |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|---|--|
| | | | <p>h congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p> | |
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | For AE Acute kidney injury: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | 'Is the adverse event serious?' is marked as YES, but responses to all of the seriousness criteria are NO. At least one seriousness criterion is expected to be YES for serious events. Please review and update as appropriate. |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|--|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? NO Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO | Initial Entry |
|---|-----------------|------------------|--|---------------|

8. Is this adverse event the result of a study Medication Error?
 If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <p>Data Entry:</p> NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------|--------------------------|
| Nov-13-2020 12:26:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |

Header Text: c4591001
Visit: Logs - Unscheduled
Form Version: 22-Apr-2020 21:02
Site No: 1097
Subject No: 10971061
Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History
Form Status: Data Complete, Locked, Frozen
Site Name: (1097) Main Street Physician's Care - Waterway
Subject Initials: ---
Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|---------------------------|---|---|
| Nov-13-2020 12:01:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Nov-13-2020 12:01:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: CONCOMITANT DRUG TREA TMENT | Transcription Error |
| Nov-13-2020 11:33:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | clinical: if the causality was related to medication then CRF should be updated to reflect Con MEDICATION not Con NON-DRUG treatment. Pls enter offending medication on CRF as well. |
| Nov-13-2020 11:01:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | The subject was being weaned off the suspect pain medication. |
| Nov-11-2020 17:21:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | clinical: pls clarify response-subject was being weaned off what? What was non drug treatment? |
| Nov-11-2020 15:33:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Subject was being weaned off. |
| Nov-10-2020 09:17:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | clinical: pls advise on nature of con non-drug treatment. Thanks |
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s) , this event is due to: CONCOMITANT NON-DRUG TREATMENT | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|------------------|--------------------------------------|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |
|---|-----------------|------------------|--------------------------------------|---------------|

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED WITH SEQUELAE | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Nov-06-2020 11:21:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Nov-07-2020 08:54:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020426230 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|-----------------------------------|---------------|
| Jan-25-2021 14:56:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: Jan/25/2021 | Initial Entry |

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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I. Select appropriate response - Is participant willing to return for Vaccination 3?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Feb-24-2021 08:29:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2 | Transcription Error |
| Jan-26-2021 14:16:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Jan-26-2021 14:16:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is NOT willing to return for Vaccination 3 OR otherwise not eligible | got Covid vaccine at visit 1&2. |
| Jan-25-2021 22:13:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Jan-25-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Jan-25-2021 14:56:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Jan-27-2021 14:28:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/25/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|---|----------------------|---------------------------|--|
| Feb-24-2021 16:13:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Closed | Auto closed by Validation Check: VC_DS001_35 |
| Feb-24-2021 08:30:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Feb-24-2021 06:27:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | DM Requery#1: Thank you for previous query response, the form has been unfrozen now kindly update the corresponding data accordingly else clarify. |
| Feb-23-2021 12:47:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | please unfreeze the page that we need to update to fix, FURTHER VACCINATION CONFIRMATION |
| Feb-22-2021 18:54:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | DM RQ: Per CCG, if the subject is eligible prior to determining whether or not placebo was given at V1/V2, consider entering Participant is willing to return for Vaccination 3 and eligible and NOT confirmed to have received only placebo |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|---|----------------------|--|--|
| | | | | at Vaccination 1/2 |
| Feb-22-2021 09:24:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: A nswered | pt received real IP at the beginning of study and does not qualify for additional vaccinations |
| Feb-22-2021 08:15:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: O pened | DMW7349437;Primary Reason for Unblinding is "ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION", but "Participant is willing to return for Vaccination 3" is not selected in the Further Vaccination Confirmation CRF. Please review and update as appropriate. |
| Jan-27-2021 14:28:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : ASSESS E LIGIBILI TY FOR AD DITIONAL VACCINAT ION | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971061

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|---|---|
| Nov-25-2020 01:31:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Nov-24-2020 15:41:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | updated |
| Nov-23-2020 00:17:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Re-query: Thank you for response; however Illness detail form at POT_COVID_ILL visit is still left blank. Please review and provide missing data or else clarify. |
| Nov-20-2020 10:59:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | data is correct as entered. |
| Nov-19-2020 07:32:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Kindly review and complete 'Health Care Utilization, Illness Details form' at POT_COVID_ILL visit. Thank you. |
| Nov-16-2020 16:36:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-02-2020 08:09:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-28-2020 15:57:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|-----------------------------------|---------------|
| Nov-16-2020 16:36:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Nov/12/2020 | Initial Entry |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

| | | | | |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Sep-02-2020 08:09:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/28/2020 | Initial Entry |
| Aug-28-2020 15:57:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/28/2020 | Initial Entry |

090177e196ae3ebe\Final\Final On: 01-Apr-2021 04:59 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971061

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-21-2020 22:57:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |