

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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 |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Sep/9/2020 |
|----|--------------|---|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [11711212] |
| 2. | Birth Date: | (b) (6)/1987 |
| 3. | Sex: | MALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | ASIAN |
| 6. | Racial Designation: | |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Sep/9/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|---|------------|
| 1. | Date of Completion/Discontinuation /Death | Sep/9/2020 |
| 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: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Form Comments

Medical History Details

| | | |
|----|--|--------------------------------|
| 1. | Line/MH Number: | Not Applicable _____ [] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | Not Applicable _____ [] |
| | Start Date: | Not Applicable _____ // |
| | Ongoing: | Not Applicable _____ |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|------------|
| 1. | Date: | Sep/9/2020 |
| 2. | Weight: | [162.8] |
| 3. | Unit: | LB |
| 4. | Height: | [67.0] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [25.5] |

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [97.7] |
| | Unit: | F |
| | Temperature Location: | FOREHEAD |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|------------|
| 1. | Randomization Date : | Sep/9/2020 |
| 2. | Randomization Number: | [85864] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Sep/9/2020 |
| 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 | [BP9HFM] |
| 5.b | Sample ID | [BP9HFN] |
| 5.c | Sample ID | [BP9HFP] |
| 5.d | Sample ID | [BRTT2G] |
| 5.e | Sample ID | [BRTT2H] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/9/2020 |
| 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 | [BP0ZCR] |
|-----|-----------|----------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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: | Sep/9/2020 16:07 |
| 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 |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Reactogenicity Diary

| | | |
|----|--|--|
| 1. | Select appropriate response - Reactogenicity diary collection | NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT |
|----|--|--|

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Oct/16/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Oct/16/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [96.3] |
| | Unit: | F |
| | Temperature Location: | FOREHEAD |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Oct/16/2020 |
| 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 | [BP9PXK] |
|-----|-----------|----------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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: | Oct/16/2020 15:11 |
| 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 |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Nov/18/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Nov/18/2020 |
| 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 | [BR0C5J] |
| 5.b | Sample ID | [BR0C5K] |
| 5.c | Sample ID | [BR0C5L] |
| 5.d | Sample ID | [BPHHZF] |
| 5.e | Sample ID | [BPHHZG] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Dec/07/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Dec/7/2020 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Dec/07/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Signs and Symptoms

| | | |
|----|--------------------------------|---|
| 1. | Date of Assessment: | Dec/7/2020 |
| 2. | Date of First Symptom Started: | Dec/4/2020 |
| 3. | Symptoms Ongoing? | NO Date of Last Symptom Resolved: Dec/30/2020 |

Symptoms

| | | |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms: | FEVER |
| | Was symptom present? | YES |
| 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? | YES |
| 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? | YES |
| 4.h | Symptoms: | DIARRHEA |
| | Was symptom present? | NO |
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | NO |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
on Dec/07/2020

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Symptoms - Other

| | | |
|-----|------------------------|--------------|
| 5.a | Symptoms - Other Text: | [Body Aches] |
| 5.b | Symptoms - Other Text: | [Headache] |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|------------------|------------------------------|---|----------------------------|---------------------------------|
| 1. | Dec/12/2020 | SWABBED MATERIAL | NASOPHARYNX | SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

| | | | |
|----|-------------------------------|--|--------------------------|
| 1. | Actual Date of Collection: | Dec/12/2020 | Comments |
| 2. | Specimen Type: | SWABBED MATERIAL | Comments |
| 3. | Specimen Collection Location: | NASOPHARYNX | Comments |
| 4. | Assay Code and Description: | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | Comments |
| 5. | Device Type: | SARS-COV-2 DIAGNOSTIC TEST | Comments |
| 6. | Trade Name: | OTHER | Comments |
| 7. | Test Result: | POSITIVE | Comments |
| 8. | Comments/Findings/Details: | [] | Comments |
| 9. | Trade Name Other, Specify: | [Quidel Sofia 2 SARS Antigen FIA] | Comments |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Dec/07/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | YES Date of Collection: Dec/7/2020 |
| 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 | [CV07097] |
|-----|-----------|-----------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Dec/07/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Dec/07/2020**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete**Site No:** 1171**Site Name:** (1171) Martin Diagnostic Clinic**Subject No:** 11711212**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[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: | NO |
| 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? | YES Has the subject been in intensive care due to potential COVID-19 illness? YES |
|----|--|---|

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Hospitalization Category | Hospitalization Term | Admission Date | Ongoing | Form Instance |
|----|--------------------------|----------------------|----------------|--|---------------------------------|
| 1. | HOSPITALIZATION STATUS | HOSPITAL | Dec/12/2020 | NO Discharge Date: Dec/18/2020 | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS
on Dec/07/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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[Form Audit Trail](#)

Hospitalization Details

| | | |
|----|---------------------------|--------------------------------------|
| 1. | Hospitalization Category: | HOSPITALIZATION STATUS |
| 2. | Hospitalization Term: | HOSPITAL |
| 3. | Admission Date: | Dec/12/2020 |
| 4. | Ongoing? | NO Discharge Date: Dec/18/2020 |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | 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 |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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 |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Dec/07/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Illness Details

| | | |
|----|--|--|
| 1. | Category of Clinical Event: | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | YES Respiratory Illness Diagnosis: [Covid-19 Pneumonia] Date of Diagnosis: Dec/13/2020 |
| 3. | Toxicity Grade: | 2 |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Category of Clinical Event | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance |
|----|----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. | | | | | Repeating Pages |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Dec/07/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Illness Details

| | | |
|----|--------------------------------|--|
| 1. | Category of Clinical Event: | |
| 2. | Subcategory of Clinical Event: | |
| 3. | Was a diagnosis obtained? | |
| 4. | Toxicity Grade: | |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. | | | | | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Dec/07/2020

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Lab Chemistry Details

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

Lab Result

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Category for Lab Test | Vendor Name (DE RIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|------------------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. | | | | | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Dec/07/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date: | Vital Signs Details | | | Form Instance |
|----|-------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Dec/07/2020

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Vital Signs

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

Vital Signs Details

| | | |
|----|--|-----|
| 2. | Record Identifier: | |
| | Systolic: | [] |
| | Diastolic: | [] |
| | Respiratory Rate in respirations/minute: | [] |
| | Heart Rate in beats/minute: | [] |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date: | Vital Signs Details | | Form Instance |
|----|-------|---------------------|-------------------|---------------------------------|
| 1. | | Record Identifier: | Oxygen Saturation | Repeating Pages |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Dec/07/2020

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Vital Signs

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

Vital Signs Details

| | | |
|----|-----------------------|-----|
| 2. | Record Identifier: | |
| | SPO2 Pulse Oximetry % | [] |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | | | | Repeating Pages |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Dec/07/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Oxygenation Parameters

| | | |
|----|------------------------------------|-----|
| 1. | Date Time of Assessment: | // |
| 2. | Arterial Blood Gases PaO2 (mmHg): | [] |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | [] |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Dec/07/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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. | Start Date: | // |
| 6. | Ongoing? | |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | | | | | Repeating Pages |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Imaging

| | | |
|----|-------------------------|----|
| 1. | Date of Assessment: | // |
| 2. | Location of Assessment: | |
| 3. | Type of Imaging Exam: | |
| 4. | Assessment: | |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-----------------|
| 1. | Date of Visit | Jan/8/2021 |
| 2. | Erroneous Visit | ERRONEOUS VISIT |

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|---------------|------------------------------|----------------------------|-------------|---------------------------------|
| 1. | | | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/08/2021

Form Version: 06-Jul-2020 21:54

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Microbiology Specimen

| | | |
|----|-------------------------------|-----|
| 1. | Actual Date of Collection: | // |
| 2. | Specimen Type: | |
| 3. | Specimen Collection Location: | |
| 4. | Assay Code and Description: | |
| 5. | Device Type: | |
| 6. | Trade Name: | |
| 7. | Test Result: | |
| 8. | Comments/Findings/Details: | [] |
| 9. | Trade Name Other, Specify: | [] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/08/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Respiratory Treatment

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

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Category of Clinical Event | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance |
|----|----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. | | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/08/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Illness Details

| | | |
|----|--------------------------------|--|
| 1. | Category of Clinical Event: | |
| 2. | Subcategory of Clinical Event: | |
| 3. | Was a diagnosis obtained? | |
| 4. | Toxicity Grade: | |

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|-------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. | | | | | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Jan/08/2021

Form Version: 21-Aug-2020 02:49

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Lab Chemistry Details

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

Lab Result

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Category for Lab Test | Vendor Name (DE RIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|------------------------|------------------|---------------|----------------------------|-------|---------|---------------------------------|
| 1. | | | | | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
on Jan/08/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date: | Vital Signs Details | | | Form Instance |
|----|-------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/08/2021

Form Version: 21-Aug-2020 02:50

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Vital Signs

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

Vital Signs Details

| | | |
|----|--|-----|
| 2. | Record Identifier: | |
| | Systolic: | [] |
| | Diastolic: | [] |
| | Respiratory Rate in respirations/minute: | [] |
| | Heart Rate in beats/minute: | [] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date: | Vital Signs Details | | Form Instance |
|----|-------|---------------------|-------------------|---------------------------------|
| 1. | | Record Identifier: | Oxygen Saturation | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/08/2021

Form Version: 21-Aug-2020 02:51

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Vital Signs

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

Vital Signs Details

| | | |
|----|-----------------------|-----|
| 2. | Record Identifier: | |
| | SPO2 Pulse Oximetry % | [] |

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/08/2021

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Oxygenation Parameters

| | | |
|----|------------------------------------|-----|
| 1. | Date Time of Assessment: | // |
| 2. | Arterial Blood Gases PaO2 (mmHg): | [] |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | [] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Jan/08/2021

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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. | Start Date: | // |
| 6. | Ongoing? | |

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Header Text: c4591001

Visit: POT_COVID_ILL 2

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | | | | | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** IMAGING
on Jan/08/2021

Form Version: 06-Jul-2020 21:53

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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Imaging

| | | |
|----|-------------------------|----|
| 1. | Date of Assessment: | // |
| 2. | Location of Assessment: | |
| 3. | Type of Imaging Exam: | |
| 4. | Assessment: | |

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Jan/8/2021 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Jan/8/2021 |
| 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 | [BP9PBX] |
| 5.b | Sample ID | [BP9PBY] |
| 5.c | Sample ID | [BP9PBZ] |
| 5.d | Sample ID | [BP9PC0] |
| 5.e | Sample ID | [BP9PC1] |
| 5.f | Sample ID | [BLG552] |
| 5.g | Sample ID | [BLG553] |
| 5.h | Sample ID | [BLG554] |
| 5.i | Sample ID | [BLG555] |
| 5.j | Sample ID | [BLG557] |
| 5.k | Sample ID | [BLG559] |
| 5.l | Sample ID | [BLG558] |
| 5.m | Sample ID | [BLG556] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/23/2020

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-----------------|
| 1. | Date of Visit | Dec/23/2020 |
| 2. | Erroneous Visit | ERRONEOUS VISIT |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/23/2020

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Form Comments](#)

[eCRF Audit Trail History](#)

Unplanned Assessments

| | | | |
|----|-------------|----------|--------------------------|
| 1. | Assessments | Not Done | Comments |
|----|-------------|----------|--------------------------|

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/23/2020

Form: CONTACT OUTCOME - UNPLANNED

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Form Comments](#)

[eCRF Audit Trail History](#)

Contact Outcome

| | | | |
|----|-------------------|--------------------------|--------------------------|
| 1. | Contact Type: | Not Done _____ | Comments |
| 2. | Was contact made? | Not Done _____ | Comments |
| 3. | Comments: | Not Done _____ [] | Comments |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/23/2020

Form: VITAL SIGNS - TEMP

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Vital Signs

| | | | |
|----|-------|-------------------------------|--------------------------|
| 1. | Date: | Not Applicable _____ // | Comments |
|----|-------|-------------------------------|--------------------------|

Vital Signs Details

| | | | |
|-----|-----------------------|--------------------------------|--------------------------|
| 2.a | Record Identifier: | Not Applicable _____ 1 | |
| | Temperature: | Not Applicable _____ [] | Comments |
| | Unit: | Not Applicable _____ | Comments |
| | Temperature Location: | Not Applicable _____ | Comments |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Dec/23/2020**Form Version:** 10-Dec-2020 02:22**Site No:** 1171**Subject No:** 11711212**Generated By:** (b) (4)**Form:** UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1171) Martin Diagnostic Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23[Form Comments](#)[eCRF Audit Trail History](#)**Unplanned Assessment Of Local Reaction**

| | | | |
|----|---------------------------|-------------------------------|--------------------------|
| 1. | Date of Assessment: | Not Applicable _____ // | Comments |
| 2. | Injection Site Location | Not Applicable _____ | Comments |
| 3. | Injection Site Body Side: | Not Applicable _____ | Comments |

Reaction

| | | | |
|-----|-------------------|-------------------------|--------------------------|
| 4.a | Reaction: | REDNESS | |
| | Reaction Present: | Not Applicable _____ | Comments |
| 4.b | Reaction: | SWELLING | |
| | Reaction Present: | Not Applicable _____ | Comments |

Symptom

| | | | |
|-----|------------------|-------------------------|--------------------------|
| 5.a | Symptom: | PAIN AT INJECTION SITE | |
| | Symptom Present: | Not Applicable _____ | Comments |
| 5.b | Symptom: | FATIGUE/TIREDNESS | |
| | Symptom Present: | Not Applicable _____ | Comments |
| 5.c | Symptom: | HEADACHE | |
| | Symptom Present: | Not Applicable _____ | Comments |
| 5.d | Symptom: | VOMITING | |
| | Symptom Present: | Not Applicable _____ | Comments |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | |
|-----|------------------|-------------------------------|--------------------------|
| 5.e | Symptom: | DIARRHEA | |
| | Symptom Present: | Not Applicable _____ | Comments |
| 5.f | Symptom: | NEW OR WORSENERED MUSCLE PAIN | |
| | Symptom Present: | Not Applicable _____ | Comments |
| 5.g | Symptom: | NEW OR WORSENERED JOINT PAIN | |
| | Symptom Present: | Not Applicable _____ | Comments |
| 5.h | Symptom: | CHILLS | |
| | Symptom Present: | Not Applicable _____ | Comments |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Nov/18/2020 |
| 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: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Disposition - Follow-Up

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

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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 | [] |
|----|-----------|-----|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|------------|---------------|---------------|--------------------|-------------------|---|---------------------------------|
| 1. DELETED | ADVERSE EVENT | 1 | SARS-CoV-2 Illness | Dec/4/2020 17:00 | NO End Date Time: Dec/30/2020 15:00 | Repeating Pages |
| 2. DELETED | ADVERSE EVENT | 2 | Covid-19 Pneumonia | Dec/13/2020 00:00 | NO End Date Time: Dec/30/2020 00:00 | Repeating Pages |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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[Form Audit Trail](#)

Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [+] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [SARS-CoV-2 Illness] |
| 4. | Start Date Time: | Dec/4/2020 17:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Dec/30/2020 15:00 |
| 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). | 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: [SARS-CoV-2 Illness] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | |
|-----|--|-------------------------------|
| 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 |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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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) | [Covid-19 Pneumonia] |
| 4. | Start Date Time: | Dec/13/2020 00:00 |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Dec/30/2020 00:00 |
| 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 |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | |
|-----|--|---|
| 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: [SARS-CoV-2 Illness] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |
| 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 |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [2020511149] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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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 | [] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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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: | // |

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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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? | |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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? | |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Feb/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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[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 per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Treatment Unblinded

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Withdrawal Of Consent

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

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Mar/8/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Mar/8/2021 |
|----|--------------|---|

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

| | | |
|----|---|--------------------|
| 1. | Date of Completion/Discontinuation /Death : | Mar/8/2021 |
| 2. | Phase of Disposition: | REPEAT SCREENING 1 |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Mar/8/2021 |
| 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 | [BR2ZL1] |
| 5.b | Sample ID | [BS8376] |
| 5.c | Sample ID | [BS8377] |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Mar/8/2021 |
| 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 | [BR2ZKF] |
|-----|-----------|----------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|------------------|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Mar/8/2021 09:34 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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 | [] |
|----|-----------|-----|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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? | |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

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

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Date of Visit

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Nov/18/2020 |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

| Name | Signature Meaning | Date | Type | Action |
|------|-------------------|------|------|--------|
|------|-------------------|------|------|--------|

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Sep-09-2020 16:49:56 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Sep-09-2020 16:54:10 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| Form | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | |
| Form | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 1 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 1 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 2 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 2 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 3 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 3 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 4 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 4 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 5 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 5 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 6 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 6 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 7 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 7 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 8 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 8 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 9 | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 9 | Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| Form | Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 1 | Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 2 | Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 3 | Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 4 | Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 5 | Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|-----------------------|----------------|
| 6 | Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | Mueed Bari (b) (4) | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: UNPLANNED VISIT - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| Form | Mar-01-2021 12:09:45 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: UNPLANNED VISIT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 1 | Mar-01-2021 12:09:45 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| Form | Mar-01-2021 12:10:29 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 1 | Mar-01-2021 12:10:29 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 2 | Mar-01-2021 12:10:29 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: Unplanned 1

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------|
| 3 | Mar-01-2021 12:10:29 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/23/2020

Form: VITAL SIGNS - TEMP - Comments

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form Version: 10-Dec-2020 02:27

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1

Form Version: 10-Dec-2020 02:27

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2.a | Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form Version: 10-Dec-2020 02:27

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

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Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2.a | Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form Version: 10-Dec-2020 02:27

Site No: 1171

Subject No: 11711212

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Form: VITAL SIGNS - TEMP - Comments

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Site Name: (1171) Martin Diagnostic Clinic

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2.a | Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form Version: 10-Dec-2020 02:22

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|---|
| Form | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records |
| | | | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|--|--------------------------------|--|
| 1 | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records <hr/> Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|--|--------------------------------|--|
| 2 | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records <hr/> Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 3 | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records |
| | | | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 4.a | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records |
| | | | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|--|--------------------------------|--|
| 4.b | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records <hr/> Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 5.a | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records |
| | | | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|--|--------------------------------|--|
| 5.b | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records <hr/> Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 5.c | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records |
| | | | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 5.d | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records |
| | | | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 5.e | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records |
| | | | Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|--|--------------------------------|--|
| 5 f | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records <hr/> Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION -
SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|--------------------------------|--|
| 5.g | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records <hr/> Not Applicable |

Header Text: c4591001

Visit: Unplanned 1

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - Comments

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| 5 h | Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Subject tested positive for SARS-CoV-2 Illness, we are awaiting medical records |
| | | | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Mar-08-2021 10:40:19 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | 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, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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

- CRF_Sign
- CRF_Sign_1

| Name | Signature Meaning | Date | Type | Action |
|---------|-------------------|---|------|-----------------------------------|
| (b) (6) | N/A | Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |

Affidavit:

N/A

| | | | | |
|-------------|----------|---|------|--------|
| Earl Martin | Approved | Mar-08-2021 11:13:29 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, EarlMartin, 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 | Mar-08-2021 10:39:08 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-------------|----------|---|------|--------|
| Earl Martin | Approved | Mar-07-2021 18:13:32 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, EarlMartin, 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.

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Feb-04-2021 13:54:59 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:
N/A

| | | | | |
|-------------|----------|---|------|--------|
| Earl Martin | Approved | Jan-28-2021 12:27:38 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

Affidavit:
By my dated signature below, I, EarlMartin, 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-08-2021 15:59:45 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:
N/A

| | | | | |
|-------------|----------|---|------|--------|
| Earl Martin | Approved | Jan-07-2021 10:20:34 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

Affidavit:
By my dated signature below, I, EarlMartin, 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-06-2021 07:52:49 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:
N/A

| | | | | |
|-------------|----------|---|------|--------|
| Earl Martin | Approved | Jan-05-2021 17:36:10 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

Affidavit:

By my dated signature below, I, EarlMartin, 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 | Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-------------|----------|---|------|--------|
| Earl Martin | Approved | Dec-15-2020 10:17:55 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, EarlMartin, 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.

| | | | | |
|------------|-----|---|--|-----------------------------------|
| Mueed Bari | N/A | Dec-14-2020 08:21:15 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|------------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-------------|----------|---|------|--------|
| Earl Martin | Approved | Dec-09-2020 13:34:16 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, EarlMartin, 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.

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|------------|-----|---|--|-----------------------------------|
| Mueed Bari | N/A | Nov-18-2020 16:27:41 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|------------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|-------------|----------|---|------|--------|
| Earl Martin | Approved | Nov-09-2020 08:31:38 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, EarlMartin, 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.

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-09-2020 16:48:42 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Sep-09-2020 16:48:42 (UTC-06:00) Central 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: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-09-2020 16:48:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Sep/9/2020 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Sep-09-2020 16:48:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11711212 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Sep-09-2020 16:48:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1987 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-09-2020 16:49:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: MALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-10-2020 08:04:20 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-09-2020 16:49:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASIAN | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|----------------------------------|--|
| Oct-18-2020 04:42:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-16-2020 15:43:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Query 1: Answered | Subject V2 conducted and completed. |
| Oct-06-2020 05:00:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM1: Thank you for the response. Please keep this query open at your end. Once visit is performed, kindly update vaccination details and rest of the visit pages and then respond to the query |
| Oct-05-2020 09:43:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Subject V2VX2L scheduled for 7/Oct/2020. Thank you. |
| Oct-05-2020 09:19:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Details on visit 'V2VX2L' are missing. Kindly consider to update or else clarify. Thank you. |
| Sep-09-2020 16:49:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-09-2020 16:53:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-09-2020 16:53:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Sep-09-2020 16:53:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 162.8 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LB | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 67.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: in | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 25.5 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 97.7 Temperature Unit: F Temperature Location:: FOREHEAD | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.7 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-10-2020 08:05:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Sep-10-2020 08:05:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Sep-10-2020 08:05:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 85864 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (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:** 1171**Site Name:** (1171) Martin Diagnostic Clinic**Subject No:** 11711212**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-10-2020 08:05:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-10-2020 08:05:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Sep-10-2020 08:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-10-2020 08:05:57 (UTC-06:00) Central 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-10-2020 08:05:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/9/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-10-2020 08:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9HFM | 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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 08:06:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9HFM | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 08:06:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9HFN | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 08:06:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9HFN | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 08:06:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9HFP | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 08:06:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9HFP | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 08:06:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRTT2G | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 08:06:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRTT2G | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-10-2020 08:06:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRTT2H | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 08:06:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRTT2H | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-10-2020 08:06:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-10-2020 08:06:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Sep-10-2020 08:06:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-10-2020 08:06:36 (UTC-06:00) Central 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-10-2020 08:06:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/9/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-10-2020 08:06:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPOZCR | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 08:06:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPOZCR | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/9/2020 16:07 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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-10-2020 08:05:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 08:05:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENICITY E-DIAR Y NOT COLLECTED FOR THIS S UBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|---|-------------------------|-----------------------------------|--|
| Oct-20-2020 01:28:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | As per site confirmation - updated PD tracker |
| Oct-19-2020 08:27:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Query 1: Answered | Subject out of window due to scheduling conflicts. Subject reeducated on study visit window compliance, and verbalized understanding. |
| Oct-19-2020 01:06:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD (b) (4) | Query 1: Opened | PDQ: Date of visit at V2_VAX2_L is out of window for 14 days from V1_DAY1_VAX1_L Dose Date. Please verify and update. Else, confirm in query response appropriately. "[(b) (4)]" |
| Oct-16-2020 15:31:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Oct/16/2020 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-----------------------------------|---------------|
| Oct-16-2020 15:31:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Oct/16/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Oct-16-2020 15:31:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Record Identifier:: 1 Temperature: 96.3 Temperature Unit: F Temperature Locati on:: FOREHEA D | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-------------------------|---------------|
| Oct-16-2020 15:31:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------|--|
| Oct-17-2020 07:50:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Saumitra Dubey (b) (4) | Query 1: Closed | Response satisfies query |
| Oct-16-2020 15:33:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Query 1: Answered | Per Sub-I, NCS. |
| Oct-16-2020 15:31:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Temperature 96.3 F is outside of Normal Range 97 - 99.5 F. |
| Oct-16-2020 15:31:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: 96.3 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-------------------------|---------------|
| Oct-16-2020 15:31:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | <u>Data Entry:</u> F | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------|---------------|
| Oct-16-2020 15:31:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | <u>Data Entry:</u> FOREHEAD | Initial Entry |

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-16-2020 15:31:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Oct-16-2020 15:31:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Oct-16-2020 15:31:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-16-2020 15:31:50 (UTC-06:00) Central 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. |
| Oct-16-2020 15:31:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: YES Date of Collection: Oct/16/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Oct-16-2020 15:31:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Sample ID: BP9PXK | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|------------------------------|---------------|
| Oct-16-2020 15:31:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: BP9PXX | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--------------------------|---------------|
| Oct-16-2020 15:32:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-16-2020 15:32:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-16-2020 15:32:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|---|---------------|
| Oct-16-2020 15:32:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Oct/16/2020 15:11 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-16-2020 15:32:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|----------------------------|---------------|
| Oct-16-2020 15:32:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: LEFT | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-16-2020 15:32:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Oct-16-2020 15:32:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OB SERVATION 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 |
|---|-----------------|-----------------------|---------------------------|---------------|
| Oct-16-2020 15:43:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-----------------------------------|---------------|
| Nov-18-2020 16:27:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Nov/18/2020 | 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, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-18-2020 16:27:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-18-2020 16:27:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Nov-18-2020 16:27:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-18-2020 16:27:49 (UTC-06:00) Central 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-18-2020 16:27:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: YES Date of Collection: Nov/18/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Nov-18-2020 16:27:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Sample ID: BR0C5J | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (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, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|------------------------------|---------------|
| Nov-18-2020 16:27:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: BR0C5J | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--|---------------|
| Nov-18-2020 16:28:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Sample ID: BR0C5K | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|------------------------------|---------------|
| Nov-18-2020 16:28:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: BR0C5K | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--|---------------|
| Nov-18-2020 16:28:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Sample ID: BR0C5L | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|------------------------------|---------------|
| Nov-18-2020 16:28:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: BR0C5L | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--|---------------|
| Nov-18-2020 16:28:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Sample ID: BPHHZF | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (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, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|------------------------------|---------------|
| Nov-18-2020 16:28:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: BPHHZF | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--|---------------|
| Nov-18-2020 16:28:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Sample ID: BPHHZG | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|------------------------------|---------------|
| Nov-18-2020 16:28:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: BPHHZG | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------|-------------------|---|
| Feb-08-2021 13:16:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 3: Closed | Response satisfies query |
| Feb-08-2021 00:22:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Closed | Response satisfies query |
| Feb-05-2021 13:14:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Not Applicable |
| Feb-05-2021 13:08:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Answered | Changed data per query |
| Jan-21-2021 07:01:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Opened | DM: Kindly review and complete 'Hospitalization Details form' at this visit. Thank you. |
| Jan-19-2021 12:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 3: Opened | Clin: It was stated in the SAE report #2020511149 that the subject was hospitalized. Please obtain subject medical records and update as appropriate CRF forms (COVID TEST, ILL SEVERE, LAB CHEM/HME, VITALA, PULSE OX, OXYGEN, VASOPRESS, IMAGING) |
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Dec/07/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1171**Site Name:** (1171) Martin Diagnostic Clinic**Subject No:** 11711212**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

| | | | | |
|---|-----------------|---------------------------|----------------------------------|--|
| Dec-14-2020 08:21:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-14-2020 08:21:13 (UTC-06:00) Central 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. |
| Dec-14-2020 08:21:13 (UTC-06:00) Central 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. |
| Dec-14-2020 08:21:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Dec/7/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------|---------------|
| Dec-14-2020 08:21:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|----------------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Dec/7/2020 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------|----------------------------------|--|
| Jan-22-2021 11:28:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Jan-18-2021 14:21:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Jan-02-2021 14:16:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Reissued:Opened | Clin: Query open until this CRF form is updated |
| Dec-30-2020 13:01:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | We are currently waiting for their medical records |
| Dec-24-2020 09:20:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: It was stated in the SAE report #2020511149 that the subject experienced a SARS-COV-2 illness, please confirm that all the information are correctly entered in the corresponding potential COVID-19 visit CRF forms |
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Dec/4/2020 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------|---|--|
| Feb-14-2021 23:42:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 2: Closed | Response satisfies query |
| Feb-10-2021 11:01:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Changed Information |
| Feb-10-2021 11:01:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: Dec/30/2020 | Changed Information |
| Feb-08-2021 15:25:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 2: Opened | Clin: There is a discrepancy between the COVID-19 PNEUMONIA end date 30Dec2020 on the AE CRF page and date of the last symptom 18Dec2020 on the CRF SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 form. Please review and update as appropriate |
| Jan-22-2021 11:28:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Jan-20-2021 16:20:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Jan-20-2021 16:20:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: | Changed Information |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1171**Site Name:** (1171) Martin Diagnostic Clinic**Subject No:** 11711212**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23

| | | | | |
|---|-----------------|---------------------------------|---|---|
| | | | Dec/18/2020 | |
| Jan-19-2021 12:32:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: It was stated in the SAE report #2020511149 that "Per subject, all symptoms were resolved for the subject by the time he was discharged ON 18Dec2020". Please review and update as appropriate the Date of Last Symptom Resolved. |
| Jan-18-2021 14:21:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: Dec/30/2020 | New Information |
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: YES | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptoms: FEVER Symptom Present: YES | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-----------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: FEVER | Initial Entry |

4.a Was symptom present?

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|---------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | <u>Data Entry:</u> YES | Initial Entry |

4.b

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | <u>Data Entry:</u> Symptoms: NEW OR INCREASED COUGH Symptom P NOresent: | Initial Entry |

4.b Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | <u>Data Entry:</u> NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | <u>Data Entry:</u> NO | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | <u>Data Entry:</u> Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1171**Site Name:** (1171) Martin Diagnostic Clinic**Subject No:** 11711212**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**4.c Symptoms:**

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NEW OR INCREASED SHORTN ESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptoms: CHILLS Symptom Present: YES | Initial Entry |

4.d Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|------------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: YES | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|--|--|--|---------------------|--|
| | | | Symptom NO Present: | |
|--|--|--|---------------------|--|

4.e Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------|--|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------|--------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------|---|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom NO Present: | Initial Entry |

4.f Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------|--|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------|--------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

4.g

| |
|--|
| |
|--|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptom NEW OR INCREASES: D SORE THROAT Symptom YES Present: | Initial Entry |

4.g Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|---------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: YES | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptoms: DIARRHEA Symptom Present: NO | Initial Entry |

4.h Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--------------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete**Site No:** 1171**Site Name:** (1171) Martin Diagnostic Clinic**Subject No:** 11711212**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23**4.i**

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptoms: VOMITING Symptom Present: NO | Initial Entry |

4.i Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:23:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:23:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptoms - Other: Body Aches | Initial Entry |

5.a Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|----------------------------------|---------------|
| Dec-14-2020 08:23:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Body Aches | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:23:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Symptoms - Other: Headache | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------|---------------|
| Dec-14-2020 08:23:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Headache | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------|--------------------------------------|--|
| Mar-10-2021 07:23:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/12/2020 | Initial Entry |
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Jan-02-2021 14:15:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Reissued:Opened | Clin: Query open until this CRF form is updated |
| Dec-30-2020 13:01:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | We are currently waiting for their medical records |
| Dec-28-2020 10:44:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: It was stated in the SAE report #2020511149 that the subject had a SARS-CoV-2 NAAT test result positive on 12Dec2020. Please update the MICROBIOLOGY SPECIMEN |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|-----------------------|--|---------------|
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWABBED MATERIAL | Initial Entry |
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NASOPHARYNX | Initial Entry |
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2 | Initial Entry |
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SARS-COV-2 DIAGNOSTIC TEST | Initial Entry |
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

7. Test Result:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: POSITIVE | Initial Entry |
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

8. Comments/Findings/Details:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Dec/07/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Mar-08-2021 17:06:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Quidel Sofia 2 SARS Antigen FI A | Initial Entry |
| Mar-08-2021 17:03:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Dec-14-2020 08:26:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-14-2020 08:21:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Dec-14-2020 08:21:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------|--|
| Jan-10-2021 14:33:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 2: Closed | Response satisfies query |
| Jan-08-2021 17:14:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Email was received stating laboratory has received the sample |
| Jan-05-2021 11:35:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 2: Opened | Clin: The central lab did not receive the nasal swab collected. Please could you confirm that the sample was sent to the central lab and that the barcode is accurate. |
| Dec-14-2020 08:21:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Dec-14-2020 08:21:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Dec/07/2020

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|--|-----------------|-----------------------|--|--|
| | | | | entered. Please review and correct as appropriate. |
| Dec-14-2020 08:21:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: YES Date of Collection: Dec/7/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:21:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Sample ID: CV07097 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|-------------------------------|---------------|
| Dec-14-2020 08:21:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: CV07097 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Dec/07/2020

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-14-2020 08:22:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Dec-14-2020 08:22:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:22:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | 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 |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:22:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Subject collected a self swab | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I.a

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | 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 |
|--|-----------------|-----------------------|----------------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: SPECIALIST | Initial Entry |

I.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|--|-----------------|-----------------------|--|-----------------|
| Jan-20-2021 16:28:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1 | New Information |
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Type of Practitioner: EMERGENCY ROOM | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|--|--|--|--|--|
| | | | Occurrence of Vis NO its or Contacts: | |
|--|--|--|--|--|

1.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: EMERGENCY ROOM | Initial Entry |

1.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------|--|---|
| Jan-22-2021 11:29:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Jan-20-2021 16:28:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Jan-20-2021 16:28:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | New Information |
| Jan-19-2021 12:16:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: It was stated in the SAE report #2020511149 that the subject experienced SARS-CoV-2 illness on 04Dec2020, which required a visit to emergency room Please review and update as appropriate this CRF form. |
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

I.c

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO | Initial Entry |

I.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

I.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

1.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-----------------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: URGENT CARE | Initial Entry |

1.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

1.e

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | 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 |
|---|-----------------|-----------------------|--|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: TELEPHONE CONSULTATION | Initial Entry |

1.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

1.f

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Dec/07/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|-----------------------|---|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Type of Practitioner: OTH R Occurrence of Visits or C NO ontacts: | Initial Entry |
|---|-----------------|-----------------------|---|---------------|

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-----------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------|---------------|
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

3. Has the subject been hospitalized due to potential COVID-19 illness?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------------|---|--|
| Jan-22-2021 11:29:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Jan-20-2021 16:27:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | New Information |
| Jan-20-2021 16:27:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Has the subject been in intensiv e care due to potential COVID- 19 illness? YES | New Information |
| Jan-19-2021 12:14:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: It was stated in the SAE report #2020511149 that the subject was hospitalized from 12Dec to |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
on Dec/07/2020

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|-----------------------|--------------------------|--|
| | | | | 18Dec2020 for SARS-COV-2 illness. Please review and update as appropriate CRF forms. Please confirm if the subject was admitted in ICU |
| Dec-14-2020 08:24:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail
on Dec/07/2020

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Feb-05-2021 13:08:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Dec/07/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Hospitalization Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-05-2021 13:08:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: HOSPITALIZATION STATUS | Initial Entry |

2. Hospitalization Term:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---|
| Feb-14-2021 23:42:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Feb-10-2021 15:36:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Feb-08-2021 15:05:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Reissued:Opened | Clin: It was stated in the SAE report #2020511149 that the subject was hospitalized from 12Dec2020. Please review and update/confirm as appropriate the CRF form. |
| Feb-05-2021 13:08:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Feb-05-2021 13:08:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: HOSPITAL | Initial Entry |
| Jan-22-2021 11:30:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: It was stated in the SAE report #2020511149 that the subject was hospitalized from 12Dec to 18Dec2020 for SARS-COV-2 illness. Please |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History
on Dec/07/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|--|--|--|--|--|
| | | | | review and update as appropriate the CRF form. Please confirm if the subject was admitted in ICU |
|--|--|--|--|--|

3. Admission Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------------|
| Feb-10-2021 15:36:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/12/2020 | Transcription Error |
| Feb-05-2021 13:08:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/13/2020 | Initial Entry |

4. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-05-2021 13:08:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Discharge Date: Dec/18/2020 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. What is the treatment Identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

2. Concomitant Non-drug Treatment Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

3. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

4. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Dec-14-2020 08:25:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

6. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|--------------------------------------|---------------|
| Dec-14-2020 08:25:09 (UTC-06:00) Central | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
on Dec/07/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|--------------------|--|--|--|--|
| Time (US & Canada) | | | | |
|--------------------|--|--|--|--|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Dec/07/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Dec-14-2020 08:24:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: POTENTIAL COVID-19 ILLNESS | Initial Entry |

2. Was a diagnosis obtained for Potential COVID-19 Illness?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---|
| Feb-05-2021 12:01:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Feb-04-2021 13:56:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Feb-04-2021 13:56:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Covid-19 Pneumonia Date of Diagnosis: Dec/13/2020 | Changed Information |
| Feb-04-2021 13:56:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | Yes is selected, however, either the diagnosis details or date of diagnosis is missing. Please correct. |
| Feb-04-2021 13:56:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Feb-04-2021 13:56:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Covid-19 Pneumonia | Changed Information |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History
on Dec/07/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|---------------------------------|--------------------------|--|
| Jan-19-2021 12:22:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: It was stated in the SAE report #2020511149 that the subject experienced PNEUMONIA. Please consider in response to "Was a diagnosis obtained for Potential COVID-19 Illness" entering COVID-19 PNEUMONIA |
| Dec-14-2020 08:24:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: NO | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-------------------------|---------------|
| Dec-14-2020 08:24:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: 2 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit
on Jan/08/2021

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---|
| Jan-22-2021 04:33:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Deleted | Query is invalid or does not apply |
| Jan-22-2021 04:33:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Deleted | Query is invalid or does not apply |
| Jan-22-2021 04:33:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Deleted | Query is invalid or does not apply |
| Jan-20-2021 16:24:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Candidate | Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level. |
| Jan-20-2021 16:24:07 (UTC-06:00) Central 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. |
| Jan-20-2021 16:24:07 (UTC-06:00) Central 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. |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 2 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/08/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|--|-----------------|---------------------|----------------------------------|--|
| | | | | Please review and update as appropriate. |
| Jan-20-2021 16:24:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 | Initial Entry |

2. Erroneous Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------------------|---------------|
| Jan-20-2021 16:24:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ERRONEOUS VISIT | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------|---------------|
| Jan-20-2021 16:24:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_B | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit
Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Jan-08-2021 15:59:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-08-2021 15:59:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_A1 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1171**Site Name:** (1171) Martin Diagnostic Clinic**Subject No:** 11711212**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 12:23[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-08-2021 16:00:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-08-2021 16:00:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Jan-08-2021 16:02:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-08-2021 16:00:56 (UTC-06:00) Central 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. |
| Jan-08-2021 16:00:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/8/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-08-2021 16:02:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9PBX | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:02:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9PBX | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:02:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9PBY | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:02:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9PBY | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:02:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9PBZ | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:02:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9PBZ | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:02:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9PC0 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:02:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9PC0 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:03:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP9PC1 | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:03:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP9PC1 | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:03:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BLG552 | Initial Entry |

5.f Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:03:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLG552 | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:03:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BLG553 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.g Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:03:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLG553 | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:03:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BLG554 | Initial Entry |

5.h Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:03:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLG554 | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:03:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BLG555 | Initial Entry |

5.i Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:03:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLG555 | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:03:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BLG557 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.j Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:03:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLG557 | Initial Entry |

5.k

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:04:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BLG559 | Initial Entry |

5.k Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:04:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLG559 | Initial Entry |

5.l

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:04:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BLG558 | Initial Entry |

5.l Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:04:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLG558 | Initial Entry |

5.m

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-08-2021 16:04:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BLG556 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Jan/08/2021

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.m Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-08-2021 16:04:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLG556 | Initial Entry |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------------------------|---|
| Mar-03-2021 14:08:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Rivkah Rosen (b) (4) | Query 1: Closed | Response satisfies query |
| Mar-03-2021 09:58:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |
| Mar-03-2021 04:09:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level. |
| Mar-01-2021 12:09:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms containing data within this visit as Not Done/Not Applicable at the form level. |
| Jan-04-2021 17:02:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/23/2020 | Initial Entry |

2. Erroneous Visit

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Mar-01-2021 12:09:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ERRONEOUS VISIT | Initial Entry |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: UNPLANNED VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Assessments

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------------------|--|
| Mar-01-2021 12:09:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Mar-01-2021 12:09:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Jan-04-2021 17:08:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-04-2021 17:03:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Contact Outcome is ticked however 'CONTACT OUTCOME' form is not entered. Please review and update as appropriate. |
| Jan-04-2021 17:03:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CONTACT OUTCOME | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Contact Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------------|---------------------|
| Mar-01-2021 12:10:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Done | Initial Entry |
| Mar-01-2021 12:10:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Changed Information |
| Jan-04-2021 17:08:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: TELEPHONE VISIT | Initial Entry |

2. Was contact made?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---|
| Mar-01-2021 12:10:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Mar-01-2021 12:10:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Jan-06-2021 00:51:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | As per site confirmation - updated PD tracker |
| Jan-05-2021 10:56:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Visit was conducted over the phone |
| Jan-05-2021 01:17:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | PDQ : Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001**Visit:** Unplanned 1 - Unscheduled Visit on Dec/23/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1171**Subject No:** 11711212**Generated By:** (b) (4)**Form:** CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1171) Martin Diagnostic Clinic**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 12:23

| | | | | |
|--|-----------------|---------------------------|--|--|
| | | | | is/are entered. Please review and update as appropriate. |
| Jan-04-2021 17:08:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Contact Outcome' is selected as 'VISIT ARRANGED' but no 'VITAL SIGNS' and/or 'UNPLANNED ASSESSMENT OF LOCAL REACTION' form(s) is/are entered. Please review and update as appropriate. |
| Jan-04-2021 17:08:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Contact: Dec/23/2020 Contact Outcome: VISIT ARRANGED | Initial Entry |

3. Comments:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|--------------------------|
| Mar-02-2021 03:59:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-01-2021 12:10:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
| Mar-01-2021 12:10:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|------------------|---------------------------|--|
| Mar-01-2021 12:10:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Feb-25-2021 03:14:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | If this visit was entered in error, please update DOV as Erroneous Visit and clear data in this form and add a form level comment as 'Not applicable'. |
| Feb-23-2021 14:17:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Visit was entered in error, records have been updated into the corresponding covid illness visit |
| Feb-22-2021 02:42:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | DM : VISIT ARRANGED is recorded on CONTACT OUTCOME - UNPLANNED form. However, Not Applicable is recorded on VITAL TEMP and REACTION CRFs. Please review and update. Else, clarify. |
| Feb-18-2021 21:08:48 (UTC-06:00) Central Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Original value is correct |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form Version: 22-Apr-2020 21:04

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|------------------|---------------------------|--|
| (US & Canada) | | | | |
| Feb-07-2021 23:09:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | DM: Kindly consider updating visit details as appropriate and then forward the query to DM. Thank you. |
| Feb-05-2021 13:15:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Covid test related to this unplanned visit shall be entered under potential covid illness visit once medical records are received. |
| Jan-07-2021 02:31:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | DM: Previous response says 'awaiting medical records'. Therefore, please review and update data as appropriate once data is available and then answer this query. Thank you. |
| Jan-05-2021 10:59:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | This telephone visit was performed as a follow up to a SAE for subject testing positive for SARS-CoV-19 and being hospitalized. |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: CONTACT OUTCOME - UNPLANNED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|---|-------------------------|---|---|
| | | | | SAE has been documented and we are awaiting medical records. |
| Jan-04-2021 23:26:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFE SDQ PROD (b) (4) | Query 1: Opened | The following text was indicated in the comment field [covid]. For any symptoms, AEs, or other key data should be collected on the appropriate page or eDiary. If this is already in the predefined list above please choose the appropriate value. Please review and update as necessary. "[(b) (4)]" |
| Jan-04-2021 17:08:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: During ediaary follow-up subject reports of being hospitalized from 12DEC 2020 20:00 - 18DEC 2020 08:00. Subject reports testing positive for covid | Initial Entry |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Not Applicable Temperature: Not Applicable Temperature Unit: Not Applicable Temperature Location:: Not Applicable | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on
Dec/23/2020

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:27

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:09:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form Version: 10-Dec-2020 02:22

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Injection Site Location

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Injection Site Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Reaction:: Not Applicable Reaction Present Not Applicable :: e | Initial Entry |

4.a Reaction:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4.a Reaction Present:

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
|---|-----------------|---------------------|--------------------------------------|---------------|

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Reaction:: Not Applicabl e Reaction Present Not Applicabl :: e | Initial Entry |

4.b Reaction:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4.b Reaction Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Applicabl le Symptom Presen Not Applicabl t:: le | Initial Entry |

5.a Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form Version: 10-Dec-2020 02:22

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

5.a Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable | Initial Entry |

5.b Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.c Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable | Initial Entry |

5.d Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Applicable | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|--------------------|--|------------------|------------------|----------------|
| Time (US & Canada) | | (b) (4), (b) (6) | le | |
| | | | Symptom Present: | Not Applicable |

5.e Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Applicable Symptom Present: Not Applicable | Initial Entry |

5.f Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:22

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable | Initial Entry |

5.g Symptom:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Symptom Present:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom:: Not Applicable Symptom Present:: Not Applicable | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Unplanned 1 - Unscheduled Visit on Dec/23/2020

Form Version: 10-Dec-2020 02:22

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: UNPLANNED ASSESSMENT OF LOCAL REACTION - SYSTEMIC EVENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

5.h Symptom:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Symptom Present:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-04-2021 17:10:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | 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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|-----------------------------------|---------------|
| Nov-18-2020 16:28:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: Nov/18/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-18-2020 16:28:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---------------------------------|---------------|
| Nov-18-2020 16:28:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Feb-08-2021 09:40:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - Audit Trail

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------------------|
| Feb-05-2021 13:02:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | New Information |
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Dec-23-2020 17:02:51 (UTC-06:00) Central 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 |
|---|-----------------|------------------------------|-------------------|---|
| Feb-08-2021 15:26:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 3: Closed | Response satisfies query |
| Feb-08-2021 09:40:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | Changed Information |
| Feb-07-2021 21:36:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 3: Opened | Clin: Per Prot Sect 8.3.7., SAE of SARS-CoV-2 ILLNESS meets study endpoint efficacy criteria and does not qualify as AE and please should be documented only on the potential COVID-19 Illness Visit CRF forms and should not be captured on the AE CRF page. |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|---|-----------------|---------------------------------|--|--|
| Jan-06-2021 11:29:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 2: Closed | Response satisfies query |
| Jan-04-2021 17:11:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Changed data per query |
| Jan-03-2021 15:07:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 2: Opened | GPDClin: SAE report stated "The subject reported of Covid-19 illness on his eDiary again on 23Dec2020". Please confirm if it is correct. If yes, please enter corresponding info in Cov-ill modules. |
| Jan-02-2021 14:16:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Closed | Response satisfies query |
| Dec-30-2020 13:02:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | We are currently waiting for their medical records |
| Dec-25-2020 15:54:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Salim Bouguermouh (b) (4) | Query 1: Opened | Clin: It was stated in the SAE report #2020511149 that the subject experienced a SARS-COV-2 illness, please confirm that all the information are correctly entered in the corresponding potential COVID-19 visit CRF forms |
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SARS-CoV-2 Illness | Initial Entry |

4. Start Date Time:

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------------|
| Jan-12-2021 14:16:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/4/2020 17:00 | Changed Information |
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/12/2020 20:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|-----------------|
| Jan-12-2021 14:15:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Dec/30/2020 15:00 | New Information |
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Dec-23-2020 17:02:51 (UTC-06:00) Central 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 |
|--|-----------------|---------------------------|------------------|--------------------------|
| Feb-05-2021 07:46:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Deleted | Close Auto Query |
| Feb-05-2021 07:46:39 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|---|-----------------|---------------------------|--------------------------|--|
| Time (US & Canada) | | | | |
| Feb-04-2021 13:54:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Candidate | For AE SARS-CoV-2 Illness: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present. |
| Feb-04-2021 13:54:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | Changed Information |
| Feb-04-2021 13:54:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Changed Information |
| Feb-04-2021 11:57:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Reissued:Opened | SAE RECON 1: Page unlocked. Please update appropriately |
| Feb-03-2021 16:18:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Per SAE Follow-up filed on 20-JAN-2021, this was reassessed and downgraded by PI. Please unlock page so that this information can be updated per source. |
| Feb-01-2021 10:30:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | SAE RECON: AE SARS-COV-2 illness 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 |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|---|-----------------|---------------------------|--|---|
| Jan-05-2021 21:27:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Deleted | Query can be addressed internally |
| Dec-30-2020 10:20:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Dec-30-2020 10:20:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birt h defect? NO Did this serious event result in death? NO Did this serious event require o r prolong hospitalization? YES Did this serious event result in persistent or significant disabili ty/incapacity? NO Is this serious event life threate ning? NO Other medically important serio us event NO | Transcription Error |
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|--|-----------------|---------------------------|--|--|
| | | | | review and update as appropriate. |
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE SARS-CoV-2 Illness: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Did this serious event require or prolong hospitalization? YES | 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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------------|---|--------------------------|
| Dec-30-2020 12:45:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 1: Closed | Response satisfies query |
| Dec-30-2020 10:37:49 (UTC-06:00) Central 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 If Other, specify: SARS-CoV-2 Illness | Transcription Error |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|--|-----------------|-------------------------------|--|---|
| Dec-30-2020 10:36:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Dec-30-2020 10:36:14 (UTC-06:00) Central 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 | Transcription Error |
| Dec-28-2020 16:33:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 1: Opened | GPDClin: Please clarify which ConMed was considered the cause of the SAE. If no, please make the corresponding change here. |
| Dec-23-2020 17:02:51 (UTC-06:00) Central 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 TREATMENT | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Dec-23-2020 17:02:51 (UTC-06:00) Central 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 |
|--|-----------------|---------------------|---------------------------|---------------|
| Dec-23-2020 17:02:51 (UTC-06:00) Central 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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-23-2020 17:02:51 (UTC-06:00) Central 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 |
|--|-----------------|---------------------------|--|---|
| Jan-12-2021 16:03:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Jan-12-2021 16:03:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | New Information |
| Jan-12-2021 14:15:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE SARS-CoV-2 Illness: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present. |
| Dec-23-2020 17:02:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERING/RESOLVING | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-23-2020 17:02:51 (UTC-06:00) Central 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 |
|--|-----------------|------------------|----------------------------------|-----------------|
| Feb-05-2021 07:46:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | New Information |
| Jan-06-2021 07:52:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2020511149 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

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, Deleted

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|--|---------------------|
| Jan-20-2021 16:14:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Covid-19 Pneumonia | Changed Information |
| Jan-18-2021 11:40:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Pneumonia | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/13/2020 00:00 | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

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, Deleted

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

Dec/30/2020 00:00

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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 |
|---|-----------------|---------------------------|-----------------------------|---|
| Feb-11-2021 14:12:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-05-2021 13:02:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | New Information |
| Feb-01-2021 10:23:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | SAE RECON 1: AE of COVID-19 pneumonia has been invalidated in safety database. Please confirm if the event should be inactivated in Inform and update appropriately or clarify. |
| Jan-24-2021 23:59:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Deleted | Close Auto Query |
| Jan-21-2021 04:14:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Candidate | PSSR review |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|---|-----------------|---------------------------|--|---|
| Jan-20-2021 16:31:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Pneumonia has been reported to Safety as a SAE. Original value is correct |
| Jan-20-2021 16:14:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Candidate | For AE Covid-19 Pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Jan-20-2021 04:55:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON: Pneumonia(Onset date: 13Dec2020) 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 |
| Jan-19-2021 03:46:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Deleted | Query can be addressed internally |
| Jan-18-2021 11:40:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Pneumonia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Jan-18-2021 11:40:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|--|--|--|--|--|
| | | | <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> | |
|--|--|--|--|--|

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 |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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 | Initial Entry |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Deleted

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|--|--|--|---------------------------|--|
| | | | <i>If Other, specify:</i> | |
| | | | SARS-CoV-2 Illness | |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|---------------------------|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|--|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-18-2021 11:40:32 (UTC-06:00) Central 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 |
|------|----------|------|-------|--------|
|------|----------|------|-------|--------|

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Deleted

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

*** THIS REPEATING FORM HAS BEEN DELETED ***

| | | | | |
|---|-----------------|--|----------------------------------|---------------|
| Jan-24-2021 23:59:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Data Entry: 2020511149 | Initial Entry |
|---|-----------------|--|----------------------------------|---------------|

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-25-2021 19:21:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/25/2021 | Initial Entry |

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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I. Select appropriate response - Is participant willing to return for Vaccination 3?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Feb-25-2021 19:21:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-25-2021 19:21:22 (UTC-06:00) Central 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. |
| Feb-25-2021 19:21:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allo wance(s) and confirmed to ha ve received only placebo at V accination 1/2 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-25-2021 19:21:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/25/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-25-2021 19:21:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR AD DITIONAL VACCINATION | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Mar-08-2021 10:39:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/8/2021 | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Mar-08-2021 10:39:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Mar/8/2021 | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------------|---------------|
| Mar-08-2021 10:40:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/8/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Mar-08-2021 10:40:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---------------------------------|---------------|
| Mar-08-2021 10:40:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-08-2021 10:42:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Mar-08-2021 10:42:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|--|
| Mar-09-2021 08:51:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-09-2021 04:45:15 (UTC-06:00) Central 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. |
| Mar-08-2021 10:42:00 (UTC-06:00) Central 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. |
| Mar-08-2021 10:42:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/8/2021 | Initial Entry |

5.a

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------------|
| Mar-09-2021 21:21:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR2ZL1 | Transcription Error |
| Mar-09-2021 08:51:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR2ZL1 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|---|------------------------|--------------------------------|--|
| Mar-10-2021 03:57:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Closed | Auto closed by Validation Check: VC_BEETRK001_02 |
| Mar-09-2021 21:21:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Mar-09-2021 21:21:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: : BR2ZL1 | Transcription Error |
| Mar-09-2021 21:15:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW7648443;Barcode contains blank Space which is not the correct format. Please review and correct as appropriate. |
| Mar-09-2021 08:51:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: : BR2ZL1 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Mar-09-2021 08:52:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BS8376 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Mar-09-2021 08:52:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BS8376 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Mar-09-2021 08:52:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BS8377 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Mar-09-2021 08:52:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BS8377 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-08-2021 10:42:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Mar-08-2021 10:42:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Mar-09-2021 08:54:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-09-2021 04:45:15 (UTC-06:00) Central 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. |
| Mar-08-2021 10:42:23 (UTC-06:00) Central 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. |
| Mar-08-2021 10:42:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/8/2021 | Initial Entry |

5.a

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Mar-09-2021 08:54:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR2ZKF | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Mar-09-2021 08:54:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR2ZKF | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/8/2021 09:34 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|----------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------------|---------------------------|---------------|
| Mar-08-2021 10:43:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [Redacted] | Data Entry: YES | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

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1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|---|---|
| Dec-15-2020 02:13:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Added data per query |
| Dec-14-2020 08:28:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Mueed Bari (b) (4) | Query 1: Answered | Potential illness visit has been updated. |
| Dec-14-2020 01:44:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Balaji Prabur (b) (4) | Query 1: Opened | As per Illness edairy records, subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 06Dec, 07Dec and 08Dec2020. But corresponding COVID Illness visit not reported. Please Clarify. |
| Nov-18-2020 16:28:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-10-2020 08:05:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Sep-09-2020 16:53:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Nov-18-2020 16:28:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Nov/18/2020 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1171

Subject No: 11711212

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1171) Martin Diagnostic Clinic

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 12:23

| | | | | |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-10-2020 08:05:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/9/2020 | Initial Entry |
| Sep-09-2020 16:53:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/9/2020 | Initial Entry |

090177e196ae3d4b\Final\Final On: 01-Apr-2021 04:30 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1171

Site Name: (1171) Martin Diagnostic Clinic

Subject No: 11711212

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 12:23

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-09-2020 08:17:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |