

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: COHORT_SELECTION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Informed Consent

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Aug/25/2020 |
|----|--------------|--|

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [11451042] |
| 2. | Birth Date: | (b) (6)/1976 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | BLACK OR AFRICAN AMERICAN |
| 6. | Racial Designation: | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Aug/25/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Aug/25/2020 |
| 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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|--|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Allergic to penicillin] |
| | Start Date: | UNK/UNK/1976 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Allergic to Monosodium glutamate (MSG)] |
| | Start Date: | UNK/UNK/1996 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Allergic to sulfur] |
| | Start Date: | UNK/UNK/2018 |
| | Ongoing: | YES |
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Seasonal Allergies] |
| | Start Date: | Mar/UNK/2020 |
| | Ongoing: | YES |
| 1.e | Line/MH Number: | [5] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Gestational diabetes] |
| | Start Date: | UNK/UNK/2011 |
| | Ongoing: | NO End Date: UNK/UNK/2011 |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | |
|-----|--|---------------------------------|
| 1 f | Line/MH Number: | [6] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Migraines] |
| | Start Date: | UNK/UNK/1997 |
| | Ongoing: | YES |
| 1.g | Line/MH Number: | [7] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Pre-diabetic] |
| | Start Date: | UNK/UNK/2013 |
| | Ongoing: | NO End Date: UNK/UNK/2015 |
| 1 h | Line/MH Number: | [8] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Anemia] |
| | Start Date: | UNK/UNK/1990 |
| | Ongoing: | NO End Date: UNK/UNK/2012 |
| 1.i | Line/MH Number: | [9] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Stomach ulcers] |
| | Start Date: | UNK/UNK/2007 |
| | Ongoing: | NO End Date: UNK/UNK/2014 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | |
|-----|--|--------------------------------------|
| 1 j | Line/MH Number: | [10] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Gallbladder disease (inflammation)] |
| | Start Date: | Jul/UNK/1994 |
| | Ongoing: | NO End Date: Aug/UNK/1994 |
| 1 k | Line/MH Number: | [11] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Surgery for gallbladder removal] |
| | Start Date: | Aug/UNK/1994 |
| | Ongoing: | NO End Date: Aug/UNK/1994 |
| 1 l | Line/MH Number: | [12] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Roux-en-y gastric bypass] |
| | Start Date: | Oct/UNK/1998 |
| | Ongoing: | NO End Date: Oct/UNK/1998 |
| 1 m | Line/MH Number: | [13] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Bypass surgery revision] |
| | Start Date: | Jan/UNK/2015 |
| | Ongoing: | NO End Date: Jan/UNK/2015 |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | |
|-----|---|--|
| 1.n | Line/MH Number: | [14] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [LEEP surgery] |
| | Start Date: | Nov/UNK/2002 |
| | Ongoing: | NO End Date: Nov/UNK/2002 |
| 1.o | Line/MH Number: | [15] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Dilation and curettage (D&C) procedure] |
| | Start Date: | UNK/UNK/2010 |
| | Ongoing: | NO End Date: UNK/UNK/2010 |
| 1.p | Line/MH Number: | [16] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Hospitalized for bronchitis] |
| | Start Date: | May/UNK/2011 |
| | Ongoing: | NO End Date: May/UNK/2011 |
| 1.q | Line/MH Number: | [17] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [obesity] |
| | Start Date: | UNK/UNK/1998 |
| | Ongoing: | YES |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|-------------|
| 1. | Date: | Aug/25/2020 |
| 2. | Weight: | [252.0] |
| 3. | Unit: | LB |
| 4. | Height: | [67.0] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [39.5] |

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [97.9] |
| | Unit: | F |
| | Temperature Location: | FOREHEAD |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Aug/25/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|-------------|
| 1. | Randomization Date : | Aug/25/2020 |
| 2. | Randomization Number: | [64092] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Aug/25/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [2.5ml collected for both retained aliquots] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP1K85] |
| 5.b | Sample ID | [BP1K9H] |
| 5.c | Sample ID | [BP1K9J] |
| 5.d | Sample ID | [BPJ18F] |
| 5.e | Sample ID | [BPJ18G] |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Aug/25/2020 |
| 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 | [BP1K7Z] |
|-----|-----------|----------|

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Aug/25/2020 12:27 |
| 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 |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Sep/15/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/15/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|----------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [97.3] |
| | Unit: | F |
| | Temperature Location: | FOREHEAD |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Sep/15/2020 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/15/2020 |
| 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 | [BP1KH1] |
|-----|-----------|----------|

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[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/15/2020 10:37 |
| 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 |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Oct/13/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Oct/13/2020 |
| 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 | [BPJ1J4] |
| 5.b | Sample ID | [BPJ1J5] |
| 5.c | Sample ID | [BPJ1J6] |
| 5.d | Sample ID | [BP1LB7] |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Oct/13/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Oct/13/2020 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

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

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**eCRF Audit Trail History****Signs and Symptoms**

| | | |
|----|--------------------------------|---|
| 1. | Date of Assessment: | Oct/13/2020 |
| 2. | Date of First Symptom Started: | Oct/9/2020 |
| 3. | Symptoms Ongoing? | NO Date of Last Symptom Resolved: Oct/12/2020 |

Symptoms

| | | |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms: | FEVER |
| | Was symptom present? | NO |
| 4.b | Symptoms: | NEW OR INCREASED COUGH |
| | Was symptom present? | YES |
| 4.c | Symptoms: | NEW OR INCREASED SHORTNESS OF BREATH |
| | Was symptom present? | NO |
| 4.d | Symptoms: | CHILLS |
| | Was symptom present? | NO |
| 4.e | Symptoms: | NEW OR INCREASED MUSCLE PAIN |
| | Was symptom present? | NO |
| 4.f | Symptoms: | NEW LOSS OF TASTE OR SMELL |
| | Was symptom present? | NO |
| 4.g | Symptoms: | NEW OR INCREASED SORE THROAT |
| | Was symptom present? | YES |
| 4.h | Symptoms: | DIARRHEA |
| | Was symptom present? | NO |
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | NO |

Symptoms - Other

| | | | |
|-----|------------------------|-------------------------------------|--------------------------|
| 5.a | Symptoms - Other Text: | [new or increased nasal congestion] | Comments |
|-----|------------------------|-------------------------------------|--------------------------|

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.b

Symptoms - Other Text:

[new or increased nasal discharge]

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Oct/13/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Microbiology Specimen

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | NO |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [physician collected the nasal swab today in clinic] |

Aliquot

Please enter barcode for each aliquot.

| | | | |
|----------------|-----------|-----|--------------------------|
| 5-a | Sample ID | [] | Comments |
|----------------|-----------|-----|--------------------------|

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Oct/13/2020 |
| 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 | [RW80670] |
|-----|-----------|-----------|

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** HEALTH CARE UTILIZATION

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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: | NO |
| 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? | NO |
|----|--|----|

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| # | 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 on **Form:** RESPIRATORY TREATMENT
Oct/13/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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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 |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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? | NO |
| 3. | Toxicity Grade: | 1 |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Lab Chemistry Details

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

Lab Result

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/13/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/13/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | |
|-----------|-----------------------------------|---------------------------|--------------------------|
| 5.d | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Alkaline Phosphatase_PX35 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |
| 5.e | Sponsor ID: | Not Applicable _____ | Comments |
| | | [] | |
| | Test: | Bilirubin_PX21 | |
| | Result: | Not Applicable _____ | Comments |
| | | [] | |
| Not Done: | Not Applicable _____ | Comments | |
| LNMT | Not Applicable _____ | Comments | |
| | Low [] High [] Unit | | |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/13/2020

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Laboratory Data Hematology

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

Lab Result

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/13/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/13/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/13/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/13/2020

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Oct/13/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Vital Signs

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

Vital Signs Details

| | | | |
|-----|--|--------------------------------|--------------------------|
| 2.a | Record Identifier: | Not Applicable _____ 1 | |
| | Systolic: | Not Applicable _____ [] | Comments |
| | Diastolic: | Not Applicable _____ [] | Comments |
| | Respiratory Rate in respirations/minute: | Not Applicable _____ [] | Comments |
| | Heart Rate in beats/minute: | Not Applicable _____ [] | Comments |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Vital Signs

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

Vital Signs Details

| | | | |
|-----|-----------------------|--------------------------------|--------------------------|
| 2.a | Record Identifier: | Not Applicable _____ 1 | |
| | SPO2 Pulse Oximetry % | Not Applicable _____ [] | Comments |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Oxygenation Parameters

| | | | |
|----|------------------------------------|--------------------------------|--------------------------|
| 1. | Date Time of Assessment: | Not Applicable _____ // | Comments |
| 2. | Arterial Blood Gases PaO2 (mmHg): | Not Applicable _____ [] | Comments |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | Not Applicable _____ [] | Comments |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Start Date: | Not Applicable _____ // | Comments |
| 6. | Ongoing? | Not Applicable _____ | Comments |

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Oct/13/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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Imaging

| | | | |
|----|-------------------------|-------------------------------|--------------------------|
| 1. | Date of Assessment: | Not Applicable _____ // | Comments |
| 2. | Location of Assessment: | Not Applicable _____ | Comments |
| 3. | Type of Imaging Exam: | Not Applicable _____ | Comments |
| 4. | Assessment: | Not Applicable _____ | Comments |

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
on Nov/17/2020

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY on Nov/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BNW4WM] |
| 5.b | Sample ID | [BNW4RB] |
| 5.c | Sample ID | [BNW4RC] |
| 5.d | Sample ID | [BRD6LZ] |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Date of Visit

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

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death : | Oct/13/2020 |
| 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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|----|---------------|---------------|---------------|---------------------|---|---------------------------------|
| 1. | ADVERSE EVENT | 1 | Ileus | Dec/25/2020 UNK:UNK | NO End Date Time: Dec/28/2020 UNK:UNK | Repeating Pages |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Adverse Event Report

| | | |
|-----|---|---|
| 1. | Category: | ADVERSE EVENT |
| 2. | AE ID: | [1] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [Ileus] |
| 4. | Start Date Time: | Dec/25/2020 UNK:UNK |
| 5. | Is the adverse event still ongoing? | NO End Date Time: Dec/28/2020 UNK:UNK |
| 6. | Toxicity Grade: | 3 |
| 7. | Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes). | YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO |
| 8. | Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log. | NO |
| 9. | Is this event related to study treatment: | NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [it is not related to vaccine, declared as ileus. Cause is idiopathic.] |
| 10. | Latest Action Taken with Study Treatment: | NOT APPLICABLE |

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Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | |
|-----|--|--------------------|
| 11. | Was a Concomitant Medication given? | NO |
| 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 | [2021082316] |

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| # | Category | Medication Error | Start Date | Is the medication error Still Ongoing | Study Medication Errors Action | Form Instance |
|----|----------------|------------------|----------------|---------------------------------------|--------------------------------|---------------------------------|
| 1. | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Not Applicable | Repeating Pages |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Medication Error

| | | | |
|-----|---|--------------------------------|--------------------------|
| 1. | Category: | Not Applicable _____ | Comments |
| 2. | Medication Error (Type of Medication Error): | Not Applicable _____ [] | Comments |
| 3. | Start Date: | Not Applicable _____ // | Comments |
| 4. | Is the medication error still ongoing? | Not Applicable _____ | Comments |
| 5. | Latest Action Taken with Study Treatment: | Not Applicable _____ | Comments |
| 6. | Was a Concomitant Medication given? | Not Applicable _____ | Comments |
| 7. | Was a Non-Drug Treatment given? | Not Applicable _____ | Comments |
| 8. | Did the Medication Error cause the subject to be discontinued from the study? | Not Applicable _____ | Comments |
| 9. | Was this medication error associated with any adverse events? | Not Applicable _____ | Comments |
| 10. | Serious Adverse Event Number: For Pfizer Use Only | Not Applicable _____ [] | Comments |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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Concomitant Medications

| | | | |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Applicable _____ [] | Comments |
| 2. | Category: | Not Applicable _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Applicable _____ | Comments |
| 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). | Not Applicable _____ [] | Comments |
| 5. | Date: | Not Applicable _____ // | Comments |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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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? | |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| | | |
|----|----------------------|----|
| 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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Lab Urinalysis

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

Lab Result

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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? | |

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/22/2021 |
| 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, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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 |
|----|---|--|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Jan/22/2021 |
| 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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Form Comments](#)

[eCRF Audit Trail History](#)

Withdrawal Of Consent

| | | | Comments |
|----|------------------------------|-------------------------------|--------------------------|
| 1. | Withdrawal of Consent Date : | Not Applicable _____ // | |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Form Comments](#)

[eCRF Audit Trail History](#)

Death Details

| | | | |
|----|---|-------------------------------|--------------------------|
| 1. | Date of Collection / Notification of Death: | Not Applicable _____ // | Comments |
|----|---|-------------------------------|--------------------------|

Cause of Death

| | | |
|----|------------------------|--------------------------------|
| 2. | Cause of Death Status: | Not Applicable _____ |
| | Cause of Death: | Not Applicable _____ [] |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/26/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Jan/26/2021 |
|----|--------------|--|

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:30

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

| | | |
|----|---|--------------------|
| 1. | Date of Completion/Discontinuation /Death : | Jan/26/2021 |
| 2. | Phase of Disposition: | REPEAT SCREENING 1 |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Jan/26/2021 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Jan/26/2021 |
| 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 | [BM9C2X] |
| 5.b | Sample ID | [BNVL27] |
| 5.c | Sample ID | [BNVL26] |
| 5.d | Sample ID | [BNVL25] |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Jan/26/2021 |
| 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 | [BM9C2R] |
|-----|-----------|----------|

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[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: | Jan/26/2021 11:00 |
| 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 |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Feb/16/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Lab Urinalysis

| | | |
|----|---------------------------------------|--------------|
| 1. | Lab Panel: | URINALYSIS |
| 2. | Lab Sub-Panel: | PREGNANCY |
| 3. | Collection Date: | Feb/16/2021 |
| 4. | Laboratory Name and Address (Derived) | [STUDY SITE] |
| 5. | Specimen Type: | URINE |

Lab Result

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Feb/16/2021 |
| 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 | [BM9C4F] |
|-----|-----------|----------|

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[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: | Feb/16/2021 10:21 |
| 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 |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

Disposition - Treatment

| | | | |
|----|--|--------------------------------|--------------------------|
| 1. | Date of Completion/Discontinuation /Death : | Not Applicable _____ // | Comments |
| 2. | Phase of Disposition: | Not Applicable _____ | Comments |
| 3. | Status: | Not Applicable _____ | Comments |
| 4. | Specify Status: | Not Applicable _____ [] | Comments |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Oct/13/2020 |

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[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: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Aug-26-2020 09:52:17 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form Version: 10-Oct-2020 16:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|--|
| 5.a | Oct-14-2020 09:49:51 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | NEW OR INCREASED NASAL CONGESTION and NEW OR INCREASED NASAL DISCHARGE |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|---|
| Form | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test <hr/> Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 1 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 2 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test <hr/> Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 3 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

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Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 4 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test <hr/> Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 5 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

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Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 6 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test <hr/> Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

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Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 7 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 8 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test <hr/> Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - Comments

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 9 | Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | volunteer has mild symptoms have not yet done the COVID 19 test |
| | | | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF -
Comments

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|-------------------------------------|
| 5.a | Oct-14-2020 09:52:31 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | duplicate entry have to remove this |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|---|
| Form | Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | minor congestion only in the nose Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 1 | Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | minor congestion only in the nose Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 2 | Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | minor congestion only in the nose |
| | | | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

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Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 3 | Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | minor congestion only in the nose Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 4 | Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | minor congestion only in the nose |
| | | | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|---|
| 5 | Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | minor congestion only in the nose Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** RESPIRATORY TREATMENT - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|-----------------------------------|
| 6 | Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | minor congestion only in the nose |
| | | | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|--|
| Form | Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | not a covid illness nasal congestion Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|--|
| 1 | Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | not a covid illness nasal congestion Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|--|
| 2 | Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | not a covid illness nasal congestion Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

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Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|--|
| 3 | Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | not a covid illness nasal congestion Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS - SEVERE - Comments

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

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Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|--|
| 4 | Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | not a covid illness nasal congestion Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2 | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 4 | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5.a | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5.a | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5.a | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5.a | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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| Item | Date | User | Comment |
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| 5.b | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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Site No: 1145

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| Item | Date | User | Comment |
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| 5.b | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site No: 1145

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| Item | Date | User | Comment |
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| 5.b | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1145

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5.b | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1145

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5.c | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5.c | Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Header Text: c4591001

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| 2 | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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| 3 | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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| 4 | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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| 5.d | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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| 5.d | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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| 5.e | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Header Text: c4591001

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| 5.e | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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| 5.e | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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| 5.f | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Header Text: c4591001

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| 5.f | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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| 5.f | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

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| 5.j | Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Oct-13-2020 11:10:18 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2 | Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 4 | Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5 | Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

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Generated By: (b) (4)

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 6 | Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| Form | Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

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| Item | Date | User | Comment |
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| 1 | Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

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Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| 2 | Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** IMAGING - Comments

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
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| 4 | Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
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| Form | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
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| 3 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
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| 4 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

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Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 5 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
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| 6 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
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| 7 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 8 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
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| 9 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
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| 10 | Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
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| Form | Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
|------|--|---------------------|----------------|
| 1 | Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

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| Item | Date | User | Comment |
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| 2 | Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
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Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
|------|--|---------------------|----------------|
| 3 | Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS -
Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
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| 4 | Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
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| 5 | Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Jan-26-2021 14:10:35 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
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| 1 | Jan-26-2021 14:10:35 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
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| Form | Jan-26-2021 14:10:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Disposition

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DEATH DETAILS CODED - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

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| Item | Date | User | Comment |
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| 1 | Jan-26-2021 14:10:47 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | 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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| Form | Jan-26-2021 14:11:17 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - Comments

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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| Item | Date | User | Comment |
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| Form | Mar-01-2021 12:12:58 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT

Form Version: 10-Dec-2020 02:29

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Mar-01-2021 12:12:58 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

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Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT

Form Version: 10-Dec-2020 02:29

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

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| Item | Date | User | Comment |
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| 2 | Mar-01-2021 12:12:58 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT

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Subject No: 11451042

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

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| Item | Date | User | Comment |
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| 3 | Mar-01-2021 12:12:58 (UTC-05:00) Eastern Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT

Form Version: 10-Dec-2020 02:29

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT - Comments

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 4 | Mar-01-2021 12:12:58 (UTC-05:00) Eastern 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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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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 | Jan-26-2021 14:08:54 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |

Affidavit:

N/A

| | | | | |
|---------|----------|---|------|--------|
| (b) (6) | Approved | Dec-08-2020 11:10:08 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-24-2020 12:30:36 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Kawsar Talaat | Approved | Nov-17-2020 14:26:28 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Nov-17-2020 09:57:27 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Kawsar Talaat | Approved | Oct-16-2020 15:18:34 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, KawsarTalaat, 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 | Oct-16-2020 10:27:11 (UTC-05:00) Eastern Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Kawsar Talaat | Approved | Oct-15-2020 16:44:33 (UTC-05:00) Eastern Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, KawsarTalaat, 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.

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 09:50:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 24 JUL 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Aug-26-2020 09:50:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: STAGE 3 COHORTS | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 09:51:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Aug/25/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Aug-26-2020 09:50:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11451042 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Aug-26-2020 09:50:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1976 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-26-2020 09:51:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 09:51:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 09:51:55 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BLACK OR AFRICAN AMERIC AN | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 09:52:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/25/2020 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 09:52:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/25/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-26-2020 09:52:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Aug-26-2020 09:52:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 09:53:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Te Allergic to penici rm: llin Start Date: UNK/UNK/1976 Ongoing: YES | Initial Entry |

I.a Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 09:53:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 09:53:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Allergic to penicillin | Initial Entry |

I.a Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 09:53:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1976 | Initial Entry |

I.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-26-2020 09:53:52 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Aug-26-2020 09:54:49 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Nu 2 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---------------|--|--|---|--|
| (US & Canada) | | | number: Medical History Term: Allergic to Monosodium glutamate (MSG) Start Date: UNK/UNK/1996 Ongoing: YES | |
|---------------|--|--|---|--|

I.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 09:54:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 09:54:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Allergic to Monosodium glutamate (MSG) | Initial Entry |

I.b Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 09:54:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1996 | Initial Entry |

I.b Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-26-2020 09:54:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.c

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 09:56:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 3 Medical History Term: Allergic to sulfur Start Date: UNK/UNK/2018 Ongoing: YES | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 09:56:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 3 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 09:56:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Allergic to sulfur | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 09:56:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2018 | Initial Entry |

I.c Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-26-2020 09:56:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------------|
| Aug-26-2020 10:46:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number: 4 Medical History Term: Seasonal Allergies Start Date: Mar/UNK/2020 Ongoing: YES | Changed Information |
| Aug-26-2020 09:56:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 4 Medical History Term: Seasonal Allergies | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|---------------------------------|--|
| | | | Start Date: UNK/UNK/2020 | |
| | | | Ongoing: YES | |

I.d Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 09:56:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 09:56:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Seasonal Allergies | Initial Entry |

I.d Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|------------------------------------|--|
| Aug-26-2020 10:46:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Aug-26-2020 10:46:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/UNK/2020 | Changed Information |
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Start Date is after or equal to the first vaccination date 25/Aug/2020. Please review and update as appropriate. |
| Aug-26-2020 09:56:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2020 | Initial Entry |

I.d Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-26-2020 09:56:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.e

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------------|
| Aug-26-2020 10:00:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number: Medical History Term: Gestational diabetes Start Date: UNK/UNK/2011 Ongoing: NO End Date: UNK/UNK/2011 | Transcription Error |
| Aug-26-2020 10:00:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Line/MH Number: Medical History Term: Gestational diabetes Start Date: UNK/UNK/2011 Ongoing: NO End Date: UNK/UNK/2015 | Transcription Error |
| Aug-26-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: Medical History Term: Gestational diabetes Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2015 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

I.e Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Gestational diabetes | Initial Entry |

I.e Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------------|
| Aug-26-2020 10:00:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/2011 | Transcription Error |
| Aug-26-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> UNK/UNK/2013 | Initial Entry |

I.e Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------------|
| Aug-26-2020 10:00:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO End Date: UNK/UNK/2011 | Transcription Error |
| Aug-26-2020 09:58:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO End Date: UNK/UNK/2015 | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-26-2020 09:59:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number: 6 Medical History Ter m: Migraines | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------|--------------|
| | | | Start Date: | UNK/UNK/1997 |
| | | | Ongoing: | YES |

I.f Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 09:59:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Aug-26-2020 09:59:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Migraines | Initial Entry |

I.f Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 09:59:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1997 | Initial Entry |

I.f Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-26-2020 09:59:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

I.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-26-2020 10:01:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 7 Medical History Te rm: Pre-diabetic Start Date: UNK/UNK/2013 Ongoing: NO End Date: UNK/UNK/2015 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

I.g Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 10:01:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 10:01:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Pre-diabetic | Initial Entry |

I.g Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 10:01:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2013 | Initial Entry |

I.g Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:01:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/2015 | Initial Entry |

I.h

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 10:01:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 8 Medical History Term: Anemia Start Date: UNK/UNK/1990 Ongoing: NO End Date: UNK/UNK/2012 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

I.h Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 10:01:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 8 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-26-2020 10:01:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Anemia | Initial Entry |

I.h Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 10:01:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1990 | Initial Entry |

I.h Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:01:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/2012 | Initial Entry |

I.i

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 9 Medical History Te Stomach ulcers rm: Start Date: UNK/UNK/2007 Ongoing: NO End Date: UNK/UNK/2014 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

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Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

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I.i Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Aug-26-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 9 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Aug-26-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Stomach ulcers | Initial Entry |

I.i Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2007 | Initial Entry |

I.i Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:02:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/2014 | Initial Entry |

I.j

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 10 Medical History Term: Gallbladder disease (inflammation) Start Date: Jul/UNK/1994 Ongoing: NO End Date: Aug/UNK/1994 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

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Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

I.j Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-26-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Gallbladder disease (inflammation) | Initial Entry |

I.j Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jul/UNK/1994 | Initial Entry |

I.j Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Aug/UNK/1994 | Initial Entry |

I.k

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 10:04:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 11 Medical History Term: Surgery for gallbladder removal Start Date: Aug/UNK/1994 Ongoing: NO End Date: Aug/UNK/1994 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

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Subject No: 11451042

Generated By: (b) (4)

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1.k Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-26-2020 10:04:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11 | Initial Entry |

1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:04:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Surgery for gallbladder removal | Initial Entry |

1.k Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 10:04:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/UNK/1994 | Initial Entry |

1.k Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:04:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Aug/UNK/1994 | Initial Entry |

1.l

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-26-2020 10:59:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: r: Medical History Roux-en-y gastric b ypass Term: Start Date: Oct/UNK/1998 Ongoing: NO End Date: Oct/UNK/1998 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

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Form Status: Data Complete, Frozen, Verified

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1.1 Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-26-2020 10:59:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12 | Initial Entry |

1.1 Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 10:59:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Roux-en-y gastric bypass | Initial Entry |

1.1 Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 10:59:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/UNK/1998 | Initial Entry |

1.1 Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:59:25 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Oct/UNK/1998 | Initial Entry |

1.m

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-26-2020 11:03:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 13 r: Medical History Term: Bypass surgery revision Start Date: Jan/UNK/2015 Ongoing: NO End Date: Jan/UNK/2015 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

I.m Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-26-2020 11:03:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 13 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 11:03:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Bypass surgery revision | Initial Entry |

I.m Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 11:03:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/UNK/2015 | Initial Entry |

I.m Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 11:03:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Jan/UNK/2015 | Initial Entry |

I.n

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 11:04:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 14 Medical History Te rm: LEEP surgery Start Date: Nov/UNK/2002 Ongoing: NO End Date: Nov/UNK/2002 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

I.n Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-26-2020 11:04:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 14 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 11:04:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEEP surgery | Initial Entry |

I.n Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 11:04:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/UNK/2002 | Initial Entry |

I.n Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 11:04:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: Nov/UNK/2002 | Initial Entry |

I.o

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 11:13:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 15 Medical History Term: Dilation and curettage (D&C) procedure Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Site No: 1145

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Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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I.o Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-26-2020 11:13:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 15 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 11:13:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dilation and curettage (D&C) procedure | Initial Entry |

I.o Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 11:13:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/2010 | Initial Entry |

I.o Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 11:13:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: UNK/UNK/2010 | Initial Entry |

I.p

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-26-2020 11:14:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 16 Medical History: Hospitalized for bronchitis Term: May/UNK/2011 Start Date: May/UNK/2011 Ongoing: NO End Date: May/UNK/2011 | Initial Entry |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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Site No: 1145

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Subject Initials: ---

Generated By: (b) (4)

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1.p Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Aug-26-2020 11:14:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 16 | Initial Entry |

1.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 11:14:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Hospitalized for bronchitis | Initial Entry |

1.p Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Aug-26-2020 11:14:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: May/UNK/2011 | Initial Entry |

1.p Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 11:14:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date: May/UNK/2011 | Initial Entry |

1.q

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Feb-04-2021 12:45:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 17 Medical History Term: obesity Start Date: UNK/UNK/1998 Ongoing: YES | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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1.q Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 12:45:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 17 | Initial Entry |

1.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------------|---------------|
| Feb-04-2021 12:45:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: obesity | Initial Entry |

1.q Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------------|---------------|
| Feb-04-2021 12:45:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: UNK/UNK/1998 | Initial Entry |

1.q Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Feb-04-2021 12:45:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/25/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 252.0 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LB | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 67.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: in | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 39.5 | Initial Entry |

7.a

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 97.9 Temperature Unit: F Temperature Location:: FOREHEAD | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.9 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Aug-26-2020 10:06:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/25/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|--|
| | | | Result:: NEGATIVE | |
| | | | Not Done:: | |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Aug-26-2020 10:06:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Aug-26-2020 11:17:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/25/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Aug-26-2020 11:17:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 64092 | 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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-27-2020 10:42:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Aug-27-2020 10:42:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Aug-27-2020 10:42:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-27-2020 10:42:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-27-2020 10:42:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/25/2020 | Initial Entry |

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-27-2020 10:44:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2.5ml collected for both retained aliquots | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Aug-27-2020 10:42:50 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time
(US & Canada)

(b) (4),
(b) (6)

Sample ID: BP1K85

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|------------------------------|---------------|
| Aug-27-2020 10:42:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (4), (b) (6) | <u>Data Entry:</u> BP1K85 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|---|---------------|
| Aug-27-2020 10:43:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (4), (b) (6) | <u>Data Entry:</u> Sample ID: BP1K9H | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|------------------------------|---------------|
| Aug-27-2020 10:43:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (4), (b) (6) | <u>Data Entry:</u> BP1K9H | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|---|---------------|
| Aug-27-2020 10:43:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (4), (b) (6) | <u>Data Entry:</u> Sample ID: BP1K9J | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|------------------------------|---------------|
| Aug-27-2020 10:43:16 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (4), (b) (6) | <u>Data Entry:</u> BP1K9J | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|---|---------------|
| Aug-27-2020 10:43:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (4), (b) (6) | <u>Data Entry:</u> Sample ID: BPJ18F | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-27-2020 10:43:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPJ18F | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-27-2020 10:43:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPJ18G | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Aug-27-2020 10:43:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPJ18G | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Aug-27-2020 10:44:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Aug-27-2020 10:44:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Aug-27-2020 10:44:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Aug-27-2020 10:44:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Aug-27-2020 10:44:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Aug/25/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-27-2020 10:44:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP1K7Z | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Aug-27-2020 10:44:58 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time
(US & Canada)

(b) (4),
(b) (6)

BP1K7Z

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Aug/25/2020 12:27 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: LEFT | Initial Entry |

7. Route:

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Aug-26-2020 10:07:01 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Aug-26-2020 10:07:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-15-2020 12:56:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/15/2020 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-15-2020 12:56:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/15/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-15-2020 12:56:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Temperature: 97.3 Temperature Unit: F Temperature Location: FOREHEA : D | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-15-2020 12:56:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-15-2020 12:56:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 97.3 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-15-2020 12:56:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Sep-15-2020 12:56:58 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FOREHEAD | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:51

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(US & Canada)

(b) (4), (b) (6)

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/15/2020 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|--|
| | | | Result:: NEGATIVE | |
| | | | Not Done:: | |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Sep-15-2020 12:57:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-15-2020 13:58:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-15-2020 13:58:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Sep-15-2020 13:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-15-2020 13:58:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-15-2020 13:58:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/15/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-15-2020 13:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP1KH1 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Sep-15-2020 13:58:19 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time
(US & Canada)

(b) (4),
(b) (6)

BP1KH1

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sep/15/2020 10:37 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> LEFT | Initial Entry |

7. Route:

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSE RVATION PERIOD | Initial Entry |

11. Was the subject observed for at least the protocol specified observation period after investigational product administration?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Sep-15-2020 12:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|---|----------------------|---|--|
| Oct-15-2020 14:24:44 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Clo sed | Response satisfies query |
| Oct-14-2020 09:55:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Ans wered | volunteer came yesterday for visit 3 and had symptoms of nasal congestion, that is reported that's why the dates are same |
| Oct-14-2020 03:21:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Ope ned | DMW4962497;The Date of Visit at Visit V3_MONTH1_POSTVAX2_L is the same as the other Date of Visit at Visit COVID_A. Please review for duplication and update as appropriate. |
| Oct-13-2020 10:52:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Oct/13 /2020 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-13-2020 15:08:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-13-2020 15:08:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Oct-13-2020 15:09:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-13-2020 15:08:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-13-2020 15:08:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/13/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 15:09:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP1J4 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Oct-13-2020 15:09:06 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|--|------------------|--------|--|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | BPJ1J4 | |
|---|--|------------------|--------|--|

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 15:09:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPJ1J5 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-13-2020 15:09:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPJ1J5 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 15:09:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPJ1J6 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-13-2020 15:09:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPJ1J6 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 15:09:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP1LB7 | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-13-2020 15:09:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP1LB7 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|---|---------------------------|---------------------------|--|
| Oct-14-2020 17:49:10 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Clo sed | Response satisfies query |
| Oct-14-2020 09:48:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 4: Ans wered | patient came in on 10132020 and reported the covid illness that's why it was filled in the same date thank u |
| Oct-14-2020 03:21:17 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 4: Op ened | DMW4962496;The Date of Visit at Visit COVID_A is the same as the other Date of Visit at Visit V3_MONTH1_POSTVAX2_L. Please review for duplication and update as appropriate. |
| Oct-13-2020 11:00:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Del eted | Close Auto Query |
| Oct-13-2020 11:00:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Can didate | 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. |
| Oct-13-2020 10:59:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Del eted | Close Auto Query |
| Oct-13-2020 10:55:36 | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Del | Close Auto Query |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|-----------------|---------------------------|---|---|
| (UTC-05:00) Eastern Time (US & Canada) | | | eted | |
| Oct-13-2020 10:52:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Can didate | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate. |
| Oct-13-2020 10:52:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Can didate | 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. |
| Oct-13-2020 10:52:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Oct/1 3/202 0 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------|---------------|
| Oct-13-2020 10:52:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Date of Assessment:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------------|---|
| Oct-13-2020 10:57:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | All symptoms are reported as Not Present and there is no Other Symptom reported. Please review and update as appropriate. |
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/13/2020 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/9/2020 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO Date of Last Symptom Resolved: Oct/12/2020 | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: NO | Initial Entry |

4.a Symptoms:

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

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified
Site No: 1145 **Site Name:** (1145) Johns Hopkins School of Medicine
Subject No: 11451042 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|-----------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |
|---|-----------------|------------------|-----------------------------|---------------|

4.a Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------------|
| Oct-15-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES | Transcription Error |
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: NO | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**4.b Symptoms:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------|---|
| Oct-15-2020 13:30:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-15-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Oct-15-2020 10:04:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Transcription Error |
| Oct-14-2020 17:24:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | if the answer is yes, the data should be updated accordingly. |
| Oct-14-2020 14:10:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | yes |
| Oct-14-2020 13:13:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | per source note, subject reported new or increased cough. Please review and clarify or confirm as appropriate. |
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom s: NEW OR INCREASED S HORTNESS OF BREAT H | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

4.c Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SHORTNES S OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: NO | Initial Entry |

4.d Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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

4.e Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO | Initial Entry |

4.f Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------------|
| Oct-14-2020 14:10:37 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms NEW OR INCREASED | Transcription Error |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|---|---------------|
| (US & Canada) | | | : SORE THROAT Symptom Present: YES | |
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms Present: NEW OR INCREASED SORE THROAT Symptom Present: NO | Initial Entry |

4.g Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---------------------------|---|
| Oct-14-2020 17:24:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-14-2020 14:10:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Oct-14-2020 14:10:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Transcription Error |
| Oct-14-2020 13:20:06 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Per source, subject reported new or increased sore throat. Please review and clarify or confirm as appropriate. |
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|---|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARRHEA | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---------------|--|--|---------------------|--|
| (US & Canada) | | | Symptom Present: NO | |
|---------------|--|--|---------------------|--|

4.h Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO | Initial Entry |

4.i Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-13-2020 10:55:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------------|
| Oct-14-2020 09:50:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Symptoms - new or increased nasa Other: l congestion | Transcription Error |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History
Form Version: 10-Oct-2020 16:02 **Form Status:** Data Complete, Frozen, Verified
Site No: 1145 **Site Name:** (1145) Johns Hopkins School of Medicine
Subject No: 11451042 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 10:57:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - Other: new or increased nasal congestion new or increased nasal discharge | Initial Entry |
|---|-----------------|------------------|---|---------------|

5.a Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|--|---|-----------------------------|---|--|
| Oct-14-2020 17:24:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Closed | Discrepancy has been closed. |
| Oct-14-2020 09:50:43 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: new or increased nasal congestion | Transcription Error |
| Oct-14-2020 09:50:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | NEW OR INCREASED NASAL CONGESTION and NEW OR INCREASED NASAL DISCHARGE |
| Oct-14-2020 01:28:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Opened | Multiple concepts in the term NEW OR INCREASED NASAL CONGESTION and NEW OR INCREASED NASAL DISCHARGE. Split the term into NEW OR INCREASED NASAL CONGESTION and NEW OR INCREASED NASAL DISCHARGE and submit separately. Thank you. |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 10:57:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: new or increased nasal congestion new or increased nasal discharge | Initial Entry |
|---|-----------------|------------------|--|---------------|

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-14-2020 09:50:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms - new or increased nasal discharge Other: | Initial Entry |

5.b Symptoms - Other Text:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-14-2020 09:50:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: new or increased nasal discharge | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5. Device Type:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

7. Test Result:

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

8. Comments/Findings/Details:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-13-2020 10:58:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-13-2020 10:59:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-13-2020 10:59:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Oct-14-2020 09:53:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Closed | Close Auto Query |
| Oct-14-2020 09:51:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 4: Opened | Response to "Sample Collected?" is No, but Barcodes are present on the page. |
| Oct-14-2020 09:51:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | the self swab was not done, only one was taken here in the visit to the CIR |
| Oct-13-2020 11:04:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Closed | Close Auto Query |
| Oct-13-2020 11:04:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/13/2020 | Transcription Error |
| Oct-13-2020 11:00:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Oct-13-2020 11:00:12 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Opened | Response to "Sample Collected?" is No, but |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**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:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|---------------------------|---|--|
| (US & Canada) | | | | Barcodes are present on the page. |
| Oct-13-2020 11:00:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | 'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate. |
| Oct-13-2020 11:00:12 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Transcription Error |
| Oct-13-2020 10:59:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-13-2020 10:59:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-13-2020 10:59:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/13/2020 | Initial Entry |

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:00:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: physician collected the nasal swab today in clinic | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---|
| Oct-16-2020 10:27:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: | Transcription Error (DELETED) |
| Oct-14-2020 09:53:13 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: | duplicate deleted |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|------------------|---|---------------|
| (US & Canada) | | | | |
| Oct-13-2020 10:59:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: RW80670 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|---|----------------------|--------------------|--|
| Oct-16-2020 11:58:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Oct-16-2020 10:27:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | deleted |
| Oct-16-2020 10:27:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error (DELETED) |
| Oct-16-2020 10:24:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | DM: kindly delete the log line, if no data is to be entered. |
| Oct-14-2020 16:22:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Closed | Auto closed by Validation Check: VC_BEETRK001_01 |
| Oct-14-2020 09:53:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | duplicate deleted |
| Oct-14-2020 09:52:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | this is duplicate entry, have to remove this self swab barcode |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|---|----------------------|-------------------------------|---|
| Oct-13-2020 16:00:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW4962450;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate. |
| Oct-13-2020 10:59:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RW80670 | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**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:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-13-2020 11:00:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Oct-13-2020 11:00:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Oct-13-2020 11:00:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-13-2020 11:00:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-13-2020 11:00:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/13/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:00:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: RW80670 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|-------------|-----------------|------------------|-------------|--------------------|
| Oct-15-2020 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: CI | Response satisfies |

| | | | | |
|---|---|---|-----------------------------|--|
| Header Text: c4591001 | | | | |
| Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 | | 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: 1145 | | Site Name: (1145) Johns Hopkins School of Medicine | | |
| Subject No: 11451042 | | Subject Initials: --- | | |
| Generated By: (b) (4) | | Generated Time (GMT): 29-Mar-2021 11:44 | | |
| 11:23:43 (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | osed | query |
| Oct-15-2020 09:37:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | Sample was collected by Site Staff and a self nasal swab label was used. |
| Oct-15-2020 01:34:51 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | Barcode is not 6 characters in length. Please review and correct as appropriate. |
| Oct-15-2020 01:34:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Raised a new query |
| Oct-15-2020 01:29:40 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | following up with VRD |
| Oct-14-2020 17:47:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Candidate | following up with VRD |
| Oct-14-2020 16:22:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 2: Closed | Auto closed by Validation Check: VC_BEETRK001_01 |
| Oct-14-2020 09:54:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | corrected per query thanks |
| Oct-14-2020 09:53:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | corrected per query |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**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:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|---|---------------------------|-------------------------------|---|
| Oct-14-2020 07:57:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | DM : Thanks for the response, the barcode "RW80670" is recorded twice, please review and update as appropriate. |
| Oct-14-2020 07:55:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM : The barcode "RW80670" recorded is more than 6 characters in length, please review and update, thank you. |
| Oct-13-2020 16:18:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | need to delete the self swab, as it is collected today by the physician |
| Oct-13-2020 16:00:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 2: Opened | DMW4962449;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate. |
| Oct-13-2020 11:02:08 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | this is the barcode number entered |
| Oct-13-2020 11:00:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Barcode is not 6 characters in length. Please review and correct as appropriate. |
| Oct-13-2020 11:00:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RW80670 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO | Initial Entry |

I.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

I.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner EMERGENC : Y ROOM Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44***I.b Physician or Healthcare Professional:***

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROOM | Initial Entry |

I.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO | Initial Entry |

I.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

I.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44***I.d Physician or Healthcare Professional:***

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

I.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO | Initial Entry |

I.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: TELEPHONE CONSULTATION | Initial Entry |

I.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: NO | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-13-2020 11:05:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. What is the treatment Identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Concomitant Non-drug Treatment Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:05:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Oct-13-2020 11:06:37 (UTC-05:00) Eastern 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 |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-13-2020 11:06:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-13-2020 11:06:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Subcategory of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Was a diagnosis obtained?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**5.a Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Ident Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | |
|---------------|--|--|--|
| (US & Canada) | | | ifier: ble Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable |
|---------------|--|--|--|

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Ident Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---------------|--|--|--|--|
| (US & Canada) | | | ifier: ble Test:: Not Applica ble Result:: Not Applica ble Not Done:: Not Applica ble Lab Normal Range: Not Applica ble | |
|---------------|--|--|--|--|

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:29 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Lab Panel:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Ident Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
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| (US & Canada) | | | ifier: ble Test:: Not Applica ble Result:: Not Applica ble Not Done:: Not Applica ble Lab Normal Range: Not Applica ble | |
|---------------|--|--|--|--|

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**5.d Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Ident Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---------------|--|--|--|--|
| (US & Canada) | | | ifier: ble Test:: Not Applica ble Result:: Not Applica ble Not Done:: Not Applica ble Lab Normal Range: Not Applica ble | |
|---------------|--|--|--|--|

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44**5.g Sponsor ID:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|----------------|
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.h LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|--|-----------------|------------------|--|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Ident Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | | |
|---------------|--|--|--------------------------|--------------------|--|
| (US & Canada) | | | ifier: | ble | |
| | | | Test:: | Not Applica ble | |
| | | | Result:: | Not Applica ble | |
| | | | Not Done:: | Not Applica ble | |
| | | | Lab Normal Range: | Not Applica ble | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.i LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|-------------------|----------------|
| | | | Result:: | Not Applicable |
| | | | Not Done:: | Not Applicable |
| | | | Lab Normal Range: | Not Applicable |

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.j Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.j Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

5.j LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:07:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:09:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Oct-13-2020 11:09:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Not Appl icable Systolic:: Not Appl icable Diastolic:: Not Appl icable Respiratory Rate in respi rations/minute: Not Appl icable Heart Rate in beats/minu te: Not Appl icable | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:09:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:09:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a Diastolic:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:09:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

2.a Respiratory Rate in respirations/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:09:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a Heart Rate in beats/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:09:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:10:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-13-2020 11:10:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: Not Applicable Oxygen Saturation: Not Applicable | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:10:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:10:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

[Back to Form](#)

1. Date Time of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:10:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Arterial Blood Gases PaO2 (mmHg):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:10:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. FiO2 (Fraction of Inhaled Oxygen):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:10:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. What is the medication identifier?**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6. Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:14 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

(US & Canada)

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/13/2020 **Form:** IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Type of Imaging Exam:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Oct-13-2020 11:11:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail
on Nov/17/2020 History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-17-2020 09:57:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Nov/17/2020 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-17-2020 09:57:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_A1 | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF
on Nov/17/2020 Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-17-2020 09:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Nov-17-2020 09:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Nov-17-2020 12:28:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Nov-17-2020 09:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Nov-17-2020 09:57:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Nov/17/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-17-2020 12:28:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNW4WM | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Nov-17-2020 12:28:22 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History on Nov/17/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|------------------|--------|--|
| (UTC-05:00) Eastern Time (US & Canada) | | (b) (4), (b) (6) | BNW4WM | |
|--|--|------------------|--------|--|

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Nov-17-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNW4RB | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Nov-17-2020 12:28:31 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNW4RB | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Nov-17-2020 12:28:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNW4RC | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Nov-17-2020 12:28:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNW4RC | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Nov-24-2020 12:30:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRD6LZ | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Nov-24-2020 12:30:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRD6LZ | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

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, Locked, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-13-2020 10:52:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/13/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-13-2020 10:52:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------------|---------------|
| Oct-13-2020 10:52:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------|---|
| Feb-04-2021 12:43:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-02-2021 14:59:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | New Information |
| Feb-02-2021 14:59:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Ileus | New Information |
| Feb-02-2021 14:55:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON: The term in SDB was updated to "Ileus", which it is mentioned in safety narrative as final/correct diagnosis. Please revise and confirm if term in AE CRF should be updated to "ILEUS". Thank |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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, Frozen, Not Complete

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|---|-----------------------------|---|---|
| | | | | you. |
| Jan-28-2021 13:10:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Closed | Discrepancy has been closed. |
| Jan-28-2021 11:30:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Jan-28-2021 11:30:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: small bowel obstruction | Transcription Error |
| Jan-27-2021 17:26:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | PFETMS Oracle (b) (4) | Query 1: Opened | Clarify SMALL BOWL OBSTRUCTION as follows...Should the spelling be SMALL BOWEL OBSTRUCTION? If so, edit. Otherwise clarify. Thank you. |
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: small bowel obstruction | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Dec/25/2020 UNK:UNK | Initial Entry |

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------|-----------------------------|
| Feb-05-2021 12:54:57 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1145**Subject No:** 11451042**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1145) Johns Hopkins School of Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|---------------------------|---|---|
| Feb-04-2021 12:46:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | New Information |
| Feb-04-2021 12:46:18 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Dec/28/2020 UNK:UNK | New Information |
| Feb-03-2021 17:18:26 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Per SAE report, stop date is 28Dec2020. Please review entry and confirm or clarify as appropriate. |
| Jan-27-2021 14:36:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Jan-27-2021 14:36:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Dec/27/2020 UNK:UNK | Transcription Error |
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For small bowl obstruction End Date 27/Dec/2021, is a future date relative to when it was entered on 27/Jan/2021. Please correct. |
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO End Date Time: Dec/27/2021 UNK:UNK | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 3 | Initial Entry |

7. Is the adverse event serious?**If Yes, NOTIFY PFIZER IMMEDIATELY.**

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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-04-2021 12:44:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-02-2021 14:59:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE Ileus: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Feb-01-2021 15:19:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 2: Closed | Response satisfies query |
| Feb-01-2021 11:59:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |
| Feb-01-2021 11:59:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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 pro long hospitalization? YES Did this serious event result in persi stent or significant disability/incapa city? NO Is this serious event life threatening ? | Transcription Error |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|----------------------------|---|--|
| | | | NO Other medically important serious event NO | |
| Feb-01-2021 10:11:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 2: Opened | GPDClin: Please clarify if the SAE was life-threatening. Protocol 10.3.2 indicates life-threatening means subject at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe. |
| Jan-28-2021 11:30:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE small bowel obstruction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | For AE small bowl obstruction: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 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? | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|---|--|
| | | | YES | |
| | | | Did this serious event result in persistent or significant disability/incapacity? | |
| | | | NO | |
| | | | Is this serious event life threatening? | |
| | | | YES | |
| | | | 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.

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern 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 |
|---|-----------------|----------------------------|--|--------------------------|
| Feb-05-2021 12:55:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Feb-04-2021 20:33:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 2: Closed | Response satisfies query |
| Feb-04-2021 12:46:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | New Information |
| Feb-04-2021 12:46:59 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> | New Information |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** Logs - Unscheduled**Form Version:** 22-Apr-2020 21:02**Site No:** 1145**Subject No:** 11451042**Generated By:** (b) (4)**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1145) Johns Hopkins School of Medicine**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|-------------------------------|---|--|
| | | | it is not related to vaccine, declared as ileus. Cause is idiopathic. | |
| Feb-04-2021 12:45:36 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | Obesity is added to the Med Hx, its ongoing |
| Feb-04-2021 08:45:30 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 2: Reissued:Opened | GPDClin: The MHx was just unfrozen. Please add obesity and be clear if it was present MHx (ongoing) or past MHx (with end date). |
| Feb-03-2021 17:16:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | Per AE log, cause of AE is idiopathic. Please review data entry and confirm or clarify as appropriate. |
| Feb-02-2021 15:04:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Answered | requesting to unfreeze the sections to enter in the medical history. Thank you |
| Feb-01-2021 10:01:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 2: Opened | GPDClin: Per SAE report, the subject had obesity with gastric bypass surgery. Please add obesity in MHx module. |
| Feb-01-2021 09:50:34 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 1: Closed | Response satisfies query |
| Jan-29-2021 14:28:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Jan-29-2021 14:28:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> it is not related to vaccine, declared as ileus | Transcription Error |

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, Frozen, Not Complete

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|-------------------------------|-------------------------------|--|
| Jan-28-2021 15:10:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Quan Jason Gong (b) (4) | Query 1: Opened | GPDClin: Please confirm this causality. The 2nd vaccine dose was taken on 9/15/20, and the subject came back for vaccine #3 on 1/26/21, it means the SAE occurred before active vaccine. |
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RELATED | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: RECOVERED/RESOLVED | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-27-2021 14:36:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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15. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Feb-04-2021 12:44:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 2021082316 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Medication Error (Type of Medication Error):

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Is the medication error still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

7. Was a Non-Drug Treatment given?

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

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: MEDICATION ERROR - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

8. Did the Medication Error cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

9. Was this medication error associated with any adverse events?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

10. Serious Adverse Event Number: For Pfizer Use Only

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:04 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

5. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Jan-27-2021 14:37:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled **Form:** DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 14:08:54 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/22/2021 | Initial Entry |

Header Text: c4591001

Visit: Potential ReVax Initial Contact - Unscheduled Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Mar-08-2021 18:20:42 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Mar-08-2021 10:24:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 3: Answered | Transcription Error |
| Mar-08-2021 10:24:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 | Transcription Error |
| Mar-05-2021 16:48:15 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | Per source, the subject was confirmed to have received Placebo. Please verify data entry. |
| Feb-23-2021 13:45:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible and NOT confirmed to have received only placebo at Vaccination 1/2 | Transcription Error |
| Feb-04-2021 11:51:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-03-2021 16:45:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |
| Feb-03-2021 16:45:39 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: | Transcription Error |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact - Unscheduled **Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:25**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44

| | | | | |
|---|-----------------|---------------------------|---|---|
| | | | eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 | |
| Feb-03-2021 16:04:32 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | Per source note, subject eligibility criteria is "all remaining participants". Please verify if subject meets criteria based on local/national recommendations or protocol allowance. |
| Jan-26-2021 14:10:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-26-2021 14:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Jan-26-2021 14:09:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|---|---------------------------|-----------------------------------|--|
| Feb-26-2021 16:29:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Closed | Auto closed by Validation Check: VC_DS001_36 |
| Feb-26-2021 10:31:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Transcription Error |
| Feb-26-2021 10:31:14 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/22/2021 | Transcription Error |
| Feb-25-2021 04:01:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued: Opened | DM RQ1: Thank you for the response. Please review again and update as per query or else clarify. |
| Feb-23-2021 13:45:50 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | updated accordingly |
| Feb-23-2021 12:36:20 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW7352637;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate. |
| Jan-26-2021 14:10:28 (UTC-05:00) Eastern Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/14/2021 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

(US & Canada)

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Jan-26-2021 14:10:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION | Initial Entry |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Withdrawal of Consent Date :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-26-2021 14:10:35 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DEATH DETAILS CODED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Collection / Notification of Death:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Jan-26-2021 14:10:47 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 14:11:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/26/2021 | 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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 14:11:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Jan/26/2021 | 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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------------------------|---------------|
| Jan-26-2021 14:11:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/26/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Jan-26-2021 14:11:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---------------------------------|---------------|
| Jan-26-2021 14:11:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/26/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|--|
| | | | Result:: NEGATIVE | |
| | | | Not Done:: | |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 14:11:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-26-2021 14:11:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-26-2021 14:11:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Jan-26-2021 14:52:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-26-2021 14:11:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-26-2021 14:11:53 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/26/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Jan-26-2021 14:52:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BM9C2X | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Jan-26-2021 14:52:24 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time
(US & Canada)

(b) (4), (b) (6)

BM9C2X

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-26-2021 14:58:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNVL27 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-26-2021 14:58:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNVL27 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-26-2021 14:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNVL26 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-26-2021 14:58:19 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNVL26 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-26-2021 14:58:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNVL25 | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-26-2021 14:58:27 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNVL25 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-26-2021 14:12:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-26-2021 14:12:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Jan-26-2021 14:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-26-2021 14:12:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-26-2021 14:12:02 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/26/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Jan-26-2021 14:46:46 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BM9C2R | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Jan-26-2021 14:46:46 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time
(US & Canada)

(b) (4), (b) (6) BM9C2R

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Jan/26/2021 11:00 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> LEFT | Initial Entry |

7. Route:

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 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 |
|---|-----------------|---------------------|---------------------------|---------------|
| Jan-26-2021 14:12:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-16-2021 11:28:24 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/16/2021 | Initial Entry |

Header Text: c4591001

Visit: V102_VAX4

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:21

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINALYSIS | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: PREGNANCY | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/16/2021 | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: STUDY SITE | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: URINE | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined 113 Identifier: Test:: Choriogonadotropin Beta_PX113 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|--|--|--|--------------------------|--|
| | | | Result:: NEGATIVE | |
| | | | Not Done:: | |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 113 | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Choriogonadotropin Beta_PX113 | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-16-2021 11:29:13 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEGATIVE | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-16-2021 11:29:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-16-2021 11:29:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Feb-16-2021 14:04:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-16-2021 11:29:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-16-2021 11:29:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/16/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Feb-16-2021 14:04:11 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BM9C4F | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Feb-16-2021 14:04:11 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

(UTC-05:00) Eastern Time
(US & Canada)

(b) (4), (b) (6)

BM9C4F

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Feb/16/2021 10:21 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|----------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> LEFT | Initial Entry |

7. Route:

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 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 |
|---|-----------------|---------------------|---------------------------|---------------|
| Feb-16-2021 11:29:56 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001**Visit:** FURTHER_VACCINATION_EOT -
Unscheduled**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Version:** 10-Dec-2020 02:29**Form Status:** Data Complete, Frozen, Verified**Site No:** 1145**Site Name:** (1145) Johns Hopkins School of Medicine**Subject No:** 11451042**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:44[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

| Date | Location | User | Value | Reason |
|---|---|----------------------|--------------------------------------|---|
| Mar-01-2021 12:12:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Feb-26-2021 10:21:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |
| Feb-17-2021 04:44:45 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Incorrect query |
| Feb-16-2021 16:39:03 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW7271521;Status on the Disposition - Treatment form is COMPLETED, but Date is different than Visit 3 Date. Please review and update as appropriate. |
| Feb-16-2021 11:33:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/16/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------------|
| Mar-01-2021 12:12:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Not Applicable | Initial Entry |
| Feb-26-2021 10:21:28 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: | Transcription Error |

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Feb-16-2021 11:33:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: OPEN LABEL TREATMENT | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------------------|---|
| Mar-01-2021 12:12:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |
| Mar-01-2021 05:12:09 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Closed | Response satisfies query |
| Feb-26-2021 10:21:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Answered | Transcription Error |
| Feb-26-2021 10:21:38 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Transcription Error |
| Feb-25-2021 05:16:49 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | CLINQUERY: EOT2 (open label phase) is marked as COMPLETED but subject has not attended V103 (1 month follow up). Please review if this page has been completed prematurely prior to V103; if so, please clear this page. Thank you. |
| Feb-23-2021 06:45:23 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Candidate | CLINQUERY: EOT2 (open label phase) is marked as COMPLETED but subject has not attended V103 (1 month follow up). Please review if this page has been completed prematurely prior to V103; if so, please |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Verified

Site No: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

| | | | | |
|---|-----------------|---------------------|---------------------------------|---|
| | | | | clear this page. Thank you. |
| Feb-23-2021 06:45:05 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | query raised in error |
| Feb-23-2021 06:43:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: EOT2 (open label phase) is marked as COMPLETED but subject has not attended V103 (1 month follow up). Please review if this page has been completed prematurely prior to V103; if so, please clear this page. Thank you. |
| Feb-16-2021 11:33:48 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |

4. Specify Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------|
| Mar-01-2021 12:12:58 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1145

Subject No: 11451042

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1145) Johns Hopkins School of Medicine

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:44

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1. Subject Status

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Oct-13-2020 10:52:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Aug-26-2020 11:17:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Aug-26-2020 09:52:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-13-2020 10:52:33 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/13/2020 | Initial Entry |
| Aug-26-2020 11:17:00 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/25/2020 | Initial Entry |
| Aug-26-2020 09:52:37 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Aug/25/2020 | Initial Entry |

090177e196ae2fe3\Final\Final On: 01-Apr-2021 03:55 (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: 1145

Site Name: (1145) Johns Hopkins School of Medicine

Subject No: 11451042

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:44

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------|--|---------------|
| Oct-15-2020 16:44:22 (UTC-05:00) Eastern Time (US & Canada) | ACV0PFEINFP6000 | Kawsar Talaat (b) (4) | Data Entry: Click Here to Enable | Initial Entry |