

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[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<br>- Protocol version                           | 06 OCT 2020     |
| 2. | Select appropriate response<br>- What cohort does the<br>subject belong to? | STAGE 3 COHORTS |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Informed Consent**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Oct/27/2020 |
|----|--------------|--|

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

**Form Version:** 15-Sep-2020 21:54

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Demography**

|    |                                 |  |
|----|---------------------------------|--|
| 1. | Subject ID                      | [12641229]                                 |
| 2. | Birth Date:                     | (b) (6)/1958                               |
| 3. | Sex:                            | MALE                                       |
| 4. | Ethnicity:                      | HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE                                      |
| 6. | Racial Designation:             |  |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Oct/27/2020 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:00

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** INCLUSION/EXCLUSION CRITERIA

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:52

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Screening**

|    |   |             |
|----|---|-------------|
| 1. | Date of Completion/Discontinuation /Death | Oct/27/2020 |
| 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:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Medical History Details**

|     |  |                                 |
|-----|--|---------------------------------|
| 1.a | Line/MH Number:  | [1]                             |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [Hypertension]                  |
|     | Start Date:  | UNK/UNK/2010                    |
|     | Ongoing:   | YES                             |
| 1.b | Line/MH Number:  | [2]                             |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [ACL repair, left]              |
|     | Start Date:  | UNK/UNK/1990                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/1990 |
| 1.c | Line/MH Number:  | [3]                             |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [Meniscus tear repair, left]    |
|     | Start Date:  | UNK/UNK/1990                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/1990 |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** GENERAL MEDICAL HISTORY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |  |                                 |
|-----|--|---------------------------------|
| 1.d | Line/MH Number:  | [4]                             |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [Meniscus tear repair, right]   |
|     | Start Date:  | UNK/UNK/2016                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/2016 |
| 1.e | Line/MH Number:  | [5]                             |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [Lupus]                         |
|     | Start Date:  | UNK/UNK/2010                    |
|     | Ongoing:   | YES                             |
| 1.f | Line/MH Number:  | [6]                             |
|     | Disease/Syndrome<br>/Surgery/Non-Drug<br>Allergies/Drug Allergies: | [Vasectomy]                     |
|     | Start Date:  | UNK/UNK/1991                    |
|     | Ongoing:   | NO<br>End Date:<br>UNK/UNK/1991 |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** HIV STATUS

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**HIV Status**

|    |  |   |
|----|--|---|
| 1. | Select appropriate response<br>- What is the subject HIV status? | The subject is NOT known to be HIV POSITIVE |
|----|--|---|

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - BASELINE

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vital Signs**

|    |                  |             |
|----|------------------|-------------|
| 1. | Date:            | Oct/27/2020 |
| 2. | Weight:          | [97.6]      |
| 3. | Unit:            | kg          |
| 4. | Height:          | [168.7]     |
| 5. | Unit:            | cm          |
| 6. | Body Mass Index: | [34.3]      |

**Vital Signs Details**

|     |                       |          |
|-----|-----------------------|----------|
| 7.a | Record Identifier:    | 1        |
|     | Temperature:          | [36.3]   |
|     | Unit:                 | C        |
|     | Temperature Location: | FOREHEAD |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** RANDOMIZATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition**

|    |                       |             |
|----|-----------------------|-------------|
| 1. | Randomization Date :  | Oct/27/2020 |
| 2. | Randomization Number: | [273378]    |
| 3. | Randomization Group:  | [ ]         |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Oct/27/2020 |
| 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 | [BRSSB7] |
| 5.b | Sample ID | [BRSSB8] |
| 5.c | Sample ID | [BM930W] |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Oct/27/2020 |
| 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 | [BM930V] |
|-----|-----------|----------|

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** VACCINATION

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**eCRF Audit Trail History**

**Vaccination**

|     |   |   |
|-----|---|---|
| 1.  | Was there a temporary delay of vaccination?   | NO  |
| 2.  | Treatment Name  | [BLINDED THERAPY]                         |
| 3.  | Formulation:  | INJECTION                                 |
| 4.  | Dose Date Time:   | Oct/27/2020 14:26                         |
| 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                                       |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** REACTOGENICITY DIARY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

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



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Vital Signs**

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

**Vital Signs Details**

|     |                       |          |
|-----|-----------------------|----------|
| 2.a | Record Identifier:    | 1        |
|     | Temperature:          | [36.0]   |
|     | Unit:                 | C        |
|     | Temperature Location: | FOREHEAD |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Nov/16/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BM92F5] |
|-----|-----------|----------|

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[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:   | Nov/16/2020 09:52                         |
| 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                                       |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264 **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264 **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Dec/18/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [ ]                                       |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |          |
|-----|-----------|----------|
| 5.a | Sample ID | [BM92JJ] |
| 5.b | Sample ID | [BSGR11] |
| 5.c | Sample ID | [BSGR12] |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** DATE OF VISIT - ILLNESS ONSET

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Dec/10/2020 |
| 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 Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Signs and Symptoms**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date of Assessment:            | Dec/10/2020   |
| 2. | Date of First Symptom Started: | Dec/7/2020  |
| 3. | Symptoms Ongoing?              | NO<br>Date of Last Symptom Resolved:<br>Dec/15/2020 |

**Symptoms**

|     |                      |                                      |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms:            | FEVER                                |
|     | Was symptom present? | NO                                   |
| 4.b | Symptoms:            | NEW OR INCREASED COUGH               |
|     | Was symptom present? | NO                                   |
| 4.c | Symptoms:            | NEW OR INCREASED SHORTNESS OF BREATH |
|     | Was symptom present? | YES                                  |
| 4.d | Symptoms:            | CHILLS                               |
|     | Was symptom present? | NO                                   |
| 4.e | Symptoms:            | NEW OR INCREASED MUSCLE PAIN         |
|     | Was symptom present? | NO                                   |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|                         |                        |                              |
|-------------------------|------------------------|------------------------------|
| 4.f                     | Symptoms:              | NEW LOSS OF TASTE OR SMELL   |
|                         | Was symptom present?   | NO                           |
| 4.g                     | Symptoms:              | NEW OR INCREASED SORE THROAT |
|                         | Was symptom present?   | NO                           |
| 4.h                     | Symptoms:              | DIARRHEA                     |
|                         | Was symptom present?   | NO                           |
| 4.i                     | Symptoms:              | VOMITING                     |
|                         | Was symptom present?   | NO                           |
| <b>Symptoms - Other</b> |                        |                              |
| 5.a                     | Symptoms - Other Text: | [Fatigue]                    |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | 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    | <a href="#">Repeating Pages</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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### Microbiology Specimen

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE   |
| 2. | Sample Type  | NASAL_SWAB_SELF  |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Dec/17/2020  |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [Subject was currently traveling and did not bring his swab kit, swab could not be collected until his return home and discharge from hospital.] |

**Aliquot**

Please enter barcode for each aliquot.

|     |           |           |
|-----|-----------|-----------|
| 5.a | Sample ID | [RR02460] |
|-----|-----------|-----------|

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |  |
|----|--|--|
| 1. | Data Origin  | SITE   |
| 2. | Sample Type  | NASAL_SWAB   |
| 3. | Sample Collected?  | NO   |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [Subject was out of the country and subsequently hospitalized, and swab could not be collected until 17Dec20.] |

**Aliquot**

Please enter barcode for each aliquot.

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**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                     |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** HEALTH CARE UTILIZATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Treatment | Start Date | Form Instance                   |
|----|----------------------|---------------------------------------|-----------|-----------|------------|---------------------------------|
| 1. | Not Done             | Not Done                              | Not Done  | Not Done  | Not Done   | <a href="#">Repeating Pages</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Respiratory Treatment**

|    |   |                          |                          |
|----|---|--------------------------|--------------------------|
| 1. | What is the treatment Identifier?             | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 2. | Concomitant Non-drug Treatment Pre-specified: | Not Done<br>_____        | <a href="#">Comments</a> |
| 3. | Treatment:                                    | Not Done<br>_____        | <a href="#">Comments</a> |
| 4. | Treatment:                                    | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 5. | Start Date:                                   | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 6. | Ongoing?                                      | Not Done<br>_____        | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** ILLNESS DETAILS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[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                          |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Category of Clinical Event: | Subcategory of Clinical Event | Diagnosis Obtained | Toxicity Grade | Form Instance                   |
|----|-----------------------------|-------------------------------|--------------------|----------------|---------------------------------|
| 1. | Not Done                    | Not Done                      | Not Done           | Not Done       | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** ILLNESS DETAILS - SEVERE

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Illness Details**

|    |                                |                   |                          |
|----|--------------------------------|-------------------|--------------------------|
| 1. | Category of Clinical Event:    | Not Done<br>_____ | <a href="#">Comments</a> |
| 2. | Subcategory of Clinical Event: | Not Done<br>_____ | <a href="#">Comments</a> |
| 3. | Was a diagnosis obtained?      | Not Done<br>_____ | <a href="#">Comments</a> |
| 4. | Toxicity Grade:                | Not Done<br>_____ | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Category f or Lab Test | Vendor Name | Collecti on Date: | Specime n Type | Lab Result                  |          |          | Form Instan ce                  |
|----|------------------------|-------------|-------------------|----------------|-----------------------------|----------|----------|---------------------------------|
|    |                        |             |                   |                | Sponsor-Defi ned Identifier | Test:    | Resul t: |                                 |
| 1. | Not Done               | Not Do ne   | Not Don e         | Not Don e      | Not Done                    | Not Done | Not Done | <a href="#">Repeating Pages</a> |
|    |                        |             |                   |                | Not Done                    | Not Done | Not Done |                                 |
|    |                        |             |                   |                | Not Done                    | Not Done | Not Done |                                 |
|    |                        |             |                   |                | Not Done                    | Not Done | Not Done |                                 |
|    |                        |             |                   |                | Not Done                    | Not Done | Not Done |                                 |
|    |                        |             |                   |                | Not Done                    | Not Done | Not Done |                                 |
|    |                        |             |                   |                | Not Done                    | Not Done | Not Done |                                 |
|    |                        |             |                   |                | Not Done                    | Not Done | Not Done |                                 |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Lab Chemistry Details**

|    |                             |                          |                          |
|----|-----------------------------|--------------------------|--------------------------|
| 1. | Lab Panel:                  | Not Done<br>_____        | <a href="#">Comments</a> |
| 2. | Laboratory Name and Address | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 3. | Collection Date:            | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 4. | Specimen Type:              | Not Done<br>_____        | <a href="#">Comments</a> |

**Lab Result**

|     |             |                          |                          |
|-----|-------------|--------------------------|--------------------------|
| 5.a | Sponsor ID: | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
|     | Test:       | C Reactive Protein_PX329 |                          |
|     | Result:     | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____        | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |
| 5.b | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Alanine Aminotransferase_PX30                          |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____                                      | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.c | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Aspartate Aminotransferase_PX28                        |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Alkaline Phosphatase_PX35                              |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>_____                             | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.e | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Bilirubin_PX21   |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Blood Urea Nitrogen_PX47                               |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.g | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Creatinine_PX48  |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Category for Lab Test | Vendor Name (DERIVED) | Collection Date : | Specimen Type | Lab Result                 |          |          | Form Instance                   |
|----|-----------------------|-----------------------|-------------------|---------------|----------------------------|----------|----------|---------------------------------|
| 1. | Not Done              | Not Done              | Not Done          | Not Done      | Sponsor-Defined Identifier | Test:    | Result:  | <a href="#">Repeating Pages</a> |
|    |                       |                       |                   |               | Not Done                   | Not Done | Not Done |                                 |
|    |                       |                       |                   |               | Not Done                   | Not Done | Not Done |                                 |
|    |                       |                       |                   |               | Not Done                   | Not Done | Not Done |                                 |
|    |                       |                       |                   |               | Not Done                   | Not Done | Not Done |                                 |
|    |                       |                       |                   |               | Not Done                   | Not Done | Not Done |                                 |
|    |                       |                       |                   |               | Not Done                   | Not Done | Not Done |                                 |
|    |                       |                       |                   |               | Not Done                   | Not Done | Not Done |                                 |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology**Form Version:** 10-Oct-2020 16:02**Form Status:** Data Complete**Site No:** 1264**Site Name:** (1264) University of California Davis Health**Subject No:** 12641229**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Laboratory Data Hematology**

|    |                             |                          |                          |
|----|-----------------------------|--------------------------|--------------------------|
| 1. | Lab Panel:                  | Not Done<br>_____        | <a href="#">Comments</a> |
| 2. | Laboratory Name and Address | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 3. | Collection Date:            | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 4. | Specimen Type:              | Not Done<br>_____        | <a href="#">Comments</a> |

**Lab Result**

|     |             |                          |                          |
|-----|-------------|--------------------------|--------------------------|
| 5.a | Sponsor ID: | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
|     | Test:       | Hemoglobin_PX1           |                          |
|     | Result:     | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____        | <a href="#">Comments</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |
| 5.b | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Hematocrit_PX2   |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____                                      | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.c | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Erythrocytes_PX3                                       |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Platelets_PX5  |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.e | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Leukocytes_PX7   |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Neutrophils_PX608                                      |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.g | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Eosinophils_PX609                                      |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.h | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Monocytes_PX612  |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.i | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Basophils_PX610  |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |             |  |                          |
|-----|-------------|--|--------------------------|
| 5.j | Sponsor ID: | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Test:       | Lymphocytes_PX611                                      |                          |
|     | Result:     | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | Not Done:   | Not Done<br>_____<br>[ ]                               | <a href="#">Comments</a> |
|     | LNMT        | Not Done<br>_____<br>Low<br>[ ]<br>High<br>[ ]<br>Unit | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Oct-2020 15:59

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Date:    | Vital Signs Details       |                  |                   | Form Instance                   |
|----|----------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Not Done | <b>Record Identifier:</b> | <b>Systolic:</b> | <b>Diastolic:</b> | <a href="#">Repeating Pages</a> |
|    |          | Not Done                  | Not Done         | Not Done          |                                 |



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Vital Signs**

|    |       |                         |                          |
|----|-------|-------------------------|--------------------------|
| 1. | Date: | Not Done<br>_____<br>// | <a href="#">Comments</a> |
|----|-------|-------------------------|--------------------------|

**Vital Signs Details**

|     |  |                          |                          |
|-----|--|--------------------------|--------------------------|
| 2.a | Record Identifier:                       | Not Done<br>_____<br>1   |                          |
|     | Systolic:                                | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
|     | Diastolic:                               | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
|     | Respiratory Rate in respirations/minute: | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
|     | Heart Rate in beats/minute:              | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Date:    | Vital Signs Details       |                          | Form Instance                   |
|----|----------|---------------------------|--------------------------|---------------------------------|
| 1. | Not Done | <b>Record Identifier:</b> | <b>Oxygen Saturation</b> | <a href="#">Repeating Pages</a> |
|    |          | Not Done                  | Not Done                 |                                 |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Vital Signs**

|    |       |                         |                          |
|----|-------|-------------------------|--------------------------|
| 1. | Date: | Not Done<br>_____<br>// | <a href="#">Comments</a> |
|----|-------|-------------------------|--------------------------|

**Vital Signs Details**

|     |                       |                          |                          |
|-----|-----------------------|--------------------------|--------------------------|
| 2.a | Record Identifier:    | Not Done<br>_____<br>1   |                          |
|     | SPO2 Pulse Oximetry % | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Date Time of Assessment | Arterial Blood Gases PaO2 | FiO2 (Fraction of Inhaled Oxygen) | Form Instance                   |
|----|-------------------------|---------------------------|-----------------------------------|---------------------------------|
| 1. | Not Done                | Not Done                  | Not Done                          | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** OXYGENATION PARAMETERS

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Oxygenation Parameters**

|    |                                    |                          |                          |
|----|------------------------------------|--------------------------|--------------------------|
| 1. | Date Time of Assessment:           | Not Done<br>_____<br>//  | <a href="#">Comments</a> |
| 2. | Arterial Blood Gases PaO2 (mmHg):  | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |
| 3. | FiO2 (Fraction of Inhaled Oxygen): | Not Done<br>_____<br>[ ] | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | 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 | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Concomitant Medications**

|    |   |                                |                          |
|----|---|--------------------------------|--------------------------|
| 1. | What is the medication identifier?  | Not Applicable<br>_____<br>[ ] | <a href="#">Comments</a> |
| 2. | Category:   | Not Applicable<br>_____        | <a href="#">Comments</a> |
| 3. | Concomitant Medications Pre-specified:  | Not Applicable<br>_____        | <a href="#">Comments</a> |
| 4. | Medication:<br><br>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<br>_____<br>[ ] | <a href="#">Comments</a> |
| 5. | Start Date:   | Not Applicable<br>_____<br>//  | <a href="#">Comments</a> |
| 6. | Ongoing?  | Not Applicable<br>_____        | <a href="#">Comments</a> |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance                   |
|----|--------------------|------------------------|----------------|--------------------|---------------------------------|
| 1. | Not Done           | Not Done               | Not Done       | Not Done           | <a href="#">Repeating Pages</a> |



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** IMAGING

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Imaging**

|    |                         |                         |                          |
|----|-------------------------|-------------------------|--------------------------|
| 1. | Date of Assessment:     | Not Done<br>_____<br>// | <a href="#">Comments</a> |
| 2. | Location of Assessment: | Not Done<br>_____       | <a href="#">Comments</a> |
| 3. | Type of Imaging Exam:   | Not Done<br>_____       | <a href="#">Comments</a> |
| 4. | Assessment:             | Not Done<br>_____       | <a href="#">Comments</a> |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/14/2021

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/14/2021 |
| 2. | Erroneous Visit |             |

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/14/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jan/14/2021 |
| 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 | [BM92M2] |
| 5.b | Sample ID | [BSGR2Z] |
| 5.c | Sample ID | [BSGR30] |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

**Form Version:** 10-Oct-2020 15:57 **Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1264 **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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

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**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Category      | AE Identifier | Adverse Event      | Start Date         | Is the Adverse Event Still Ongoing | Form Instance                   |
|----|---------------|---------------|--------------------|--------------------|------------------------------------|---------------------------------|
| 1. | ADVERSE EVENT | 1             | Pulmonary embolism | Dec/7/2020 UNK:UNK | YES                                | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 18:51

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**Adverse Event Report**

|    |  |                      |
|----|--|----------------------|
| 1. | Category:  | ADVERSE EVENT        |
| 2. | AE ID:   | [1]                  |
| 3. | Adverse Event:<br>(If possible specify diagnosis, not individual symptoms) | [Pulmonary embolism] |
| 4. | Start Date Time:   | Dec/7/2020 UNK:UNK   |
| 5. | Is the adverse event still ongoing?  | YES                  |
| 6. | Toxicity Grade:  | 4                    |

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |  |  |
|-----|--|--|
| 7.  | <p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>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).</p> | <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?<br/>NO</p> <p>Did this serious event result in death?<br/>NO</p> <p>Did this serious event require or prolong hospitalization?<br/>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?<br/>NO</p> <p>Is this serious event life threatening?<br/>NO</p> <p>Other medically important serious event<br/>NO</p> |
| 8.  | <p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>   | NO   |
| 9.  | <p>Is this event related to study treatment:</p>   | <p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to:<br/>OTHER</p> <p>If Other, specify:<br/>[Not specified]</p>  |
| 10. | <p>Latest Action Taken with Study Treatment:</p>   | NOT APPLICABLE   |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|     |  |                      |
|-----|--|----------------------|
| 11. | Was a Concomitant Medication given?  | YES                  |
| 12. | Was a Non-Drug Treatment given?  | NO                   |
| 13. | What was the outcome of this adverse event?:                               | RECOVERING/RESOLVING |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | NO                   |
| 15. | Serious Adverse Event Number: For Pfizer Use Only                          | [2020497627]         |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Category | Medication Error | Start Date | Is the medication error Still Ongoing | Study Medication Errors Action | Form Instance                   |
|----|----------|------------------|------------|---------------------------------------|--------------------------------|---------------------------------|
| 1. |          |                  |            |                                       |                                | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

**Form Version:** 17-Jul-2020 21:54

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Medication Error**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Start Date | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------|---------------------------------|
| 1. |                            |                         |                                       |                    |            | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Concomitant Medications**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Sponsor-Defined Identifier | Category for Medication | Concomitant Medications Pre-specified | Name of Medication | Dose Description | Form Instance                   |
|----|----------------------------|-------------------------|---------------------------------------|--------------------|------------------|---------------------------------|
| 1. |                            |                         |                                       |                    |                  | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**Concomitant Medications**

|     |   |     |
|-----|---|-----|
| 1.  | What is the medication identifier?  | [ ] |
| 2.  | Category:   |     |
| 3.  | Concomitant Medications Pre-specified:  |     |
| 4.  | Medication:<br><br>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?  |     |

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**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Category | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Start Date | Form Instance                   |
|----|----------|----------------------|---------------------------------------|-----------|------------|---------------------------------|
| 1. |          |                      |                                       |           |            | <a href="#">Repeating Pages</a> |



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** RADIATION TREATMENT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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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?                                      |     |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| #  | Transfusion Type | Date of Transfusion | Form Instance                   |
|----|------------------|---------------------|---------------------------------|
| 1. |                  |                     | <a href="#">Repeating Pages</a> |

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled **Form:** DATE OF VISIT  
Visit

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

**Site No:** 1264 **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1264    **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 18:51

**Unplanned Assessments**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**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? |     |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

**Form Version:** 10-Oct-2020 15:57

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Treatment**

|    |  |             |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death : | Dec/18/2020 |
| 2. | Phase of Disposition:                      | VACCINATION |
| 3. | Status:                                    | COMPLETED   |
| 4. | Specify Status:                            | [ ]         |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

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

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264      **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

| Date of Visit |                 |             |
|---------------|-----------------|-------------|
| 1.            | Date of Visit   | Jan/27/2021 |
| 2.            | Erroneous Visit |             |

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

|    |  |   | <a href="#">Comments</a> |
|----|--|---|--------------------------|
| 1. | Select appropriate response<br>- Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3<br><br>Participant is:<br>eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2 |                          |

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

**Form Version:** 15-Sep-2020 21:53

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Disposition - Follow-Up**

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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Treatment Unblinded**

|    |                                |   |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded :     | Jan/27/2021                                   |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Withdrawal Of Consent**

|    |                                 |    |
|----|---------------------------------|----|
| 1. | Withdrawal of Consent<br>Date : | // |
|----|---------------------------------|----|



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Jan/27/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

|    |              |  |
|----|--------------|--|
| 1. | Consent Was: | OBTAINED<br>Date Written Consent Obtained<br>Jan/27/2021 |
|----|--------------|--|

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:30

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[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:** DISPOSITION - SCREENING FOR FURTHER VACCINATION

**Form Version:** 10-Dec-2020 02:31

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

|    |  |                    |
|----|--|--------------------|
| 1. | Date of Completion/Discontinuation/Death : | Jan/27/2021        |
| 2. | Phase of Disposition:                      | REPEAT SCREENING 1 |
| 3. | Status:                                    | COMPLETED          |
| 4. | Specify Status:                            | [ ]                |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | SERUM                                     |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jan/27/2021 |
| 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 | [BM92MF] |
| 5.b | Sample ID | [BSGR5T] |
| 5.c | Sample ID | [BSGR5V] |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Jan/27/2021 |
| 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 | [BRFH8G] |
|-----|-----------|----------|

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[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/27/2021 16:12 |
| 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               |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** DATE OF VISIT

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Date of Visit**

|    |                 |             |
|----|-----------------|-------------|
| 1. | Date of Visit   | Feb/17/2021 |
| 2. | Erroneous Visit |             |

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

|    |  |   |
|----|--|---|
| 1. | Data Origin  | SITE                                      |
| 2. | Sample Type  | NASAL_SWAB                                |
| 3. | Sample Collected?  | YES<br>Date of Collection:<br>Feb/17/2021 |
| 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 | [BR4FBC] |
|-----|-----------|----------|

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form:** VACCINATION

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[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/17/2021 08:15 |
| 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               |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Contact Outcome**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V105\_MONTH18

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**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:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** CONTACT OUTCOME

**Form Status:** Not Started

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:**  
FURTHER\_VACCINATION\_EOT -  
Unscheduled

**Form:** DISPOSITION - TREATMENT

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Not Started

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Disposition - Treatment**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[eCRF Audit Trail History](#)

**Subject Status**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Signed, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[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, Signed, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[Audit Trail](#)

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

- CRF\_Sign

| Name              | Signature Meaning | Date   | Type | Action |
|-------------------|-------------------|--|------|--------|
| Timothy Albertson | Approved          | Mar-11-2021 14:48:33 (UTC-08:00)<br>Pacific Time (US & Canada) | BOOK | Signed |

**Affidavit:**

By my dated signature below, I, TimothyAlbertson, 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.

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** INCLUSION/EXCLUSION CRITERIA -  
Comments

**Form Version:** 10-Oct-2020 16:00

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User                | Comment        |
|------|--|---------------------|----------------|
| Form | Oct-29-2020 08:49:04 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6) | Not Applicable |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User                | Comment  |
|------|--|---------------------|----------|
| Form | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 1    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 2    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 3    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 4    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 5    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 6    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 7    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 8    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 9    | Dec-14-2020 09:02:40 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User                | Comment  |
|------|--|---------------------|----------|
| Form | Dec-14-2020 09:04:02 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 1    | Dec-14-2020 09:04:02 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 2    | Dec-14-2020 09:04:02 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 3    | Dec-14-2020 09:04:02 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

| Item | Date   | User                | Comment  |
|------|--|---------------------|----------|
| 4    | Dec-14-2020 09:04:02 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 5    | Dec-14-2020 09:04:02 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 6    | Dec-14-2020 09:04:02 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** ILLNESS DETAILS - SEVERE - Comments

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete

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**Site Name:** (1264) University of California Davis Health

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**Generated By:** (b) (4)

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**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

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**Generated Time (GMT):** 29-Mar-2021 18:51

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Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - Comments

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
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Hematology - Comments

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**Site No:** 1264

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**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete

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Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

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| Item | Date   | User  | Comment  |
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**Form:** VITAL SIGNS - COVID - Comments

**Form Version:** 10-Oct-2020 15:59

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Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - COVID - Comments

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Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Oct-2020 16:04

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - PULSE OX ROOM AIR -  
Comments

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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Unscheduled Visit on Dec/10/2020

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Comments

**Form Version:** 10-Oct-2020 16:04

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** OXYGENATION PARAMETERS - Comments

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

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| Form | Dec-14-2020 09:07:04 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6) | Not Done |

**Header Text:** c4591001

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Unscheduled Visit on Dec/10/2020

**Form:** OXYGENATION PARAMETERS - Comments

**Form Version:** 06-Jul-2020 21:52

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| Item | Date   | User  | Comment  |
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**Header Text:** c4591001

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

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**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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VASOPRESSORS - Comments

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| Item | Date   | User  | Comment        |
|------|--|---|----------------|
| 2    | Dec-14-2020 09:22:13 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Applicable |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment        |
|------|--|---|----------------|
| 3    | Dec-14-2020 09:22:13 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Applicable |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment        |
|------|--|---|----------------|
| 4    | Dec-14-2020 09:22:13 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Applicable |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment        |
|------|--|---|----------------|
| 5    | Dec-14-2020 09:22:13 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Applicable |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - Comments

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment        |
|------|--|---|----------------|
| 6    | Dec-14-2020 09:22:13 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Applicable |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** IMAGING - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| Form | Dec-14-2020 09:22:31 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** IMAGING - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 1    | Dec-14-2020 09:22:31 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** IMAGING - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 2    | Dec-14-2020 09:22:31 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** IMAGING - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 3    | Dec-14-2020 09:22:31 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** IMAGING - Comments

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User  | Comment  |
|------|--|---|----------|
| 4    | Dec-14-2020 09:22:31 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(b) (6)<br>[Redacted]<br>[Redacted] | Not Done |

**Header Text:** c4591001

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

**Form Version:** 10-Dec-2020 02:25      **Form Status:** Data Complete, Frozen

**Site No:** 1264      **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User             | Comment   |
|------|--|------------------|---|
| 1    | Feb-03-2021 14:34:12 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4), (b) (6) | Could you please unfreeze subject 12641006? He meets eligibility criteria and since has been revaccinated |

**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Item | Date   | User                | Comment        |
|------|--|---------------------|----------------|
| Form | Jan-29-2021 11:47:43 (UTC-08:00)<br>Pacific Time (US & Canada) | (b) (4),<br>(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, Signed, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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

- CRF\_Sign

| Name              | Signature Meaning | Date   | Type | Action |
|-------------------|-------------------|--|------|--------|
| Timothy Albertson | Approved          | Mar-11-2021 14:48:33 (UTC-08:00)<br>Pacific Time (US & Canada) | BOOK | Signed |

**Affidavit:**

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

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

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

|         |     |  |  |                                   |
|---------|-----|--|--|-----------------------------------|
| (b) (6) | N/A | Jan-28-2021 08:58:08 (UTC-08:00)<br>Pacific Time (US & Canada) |  | Edit - All signatures invalidated |
|---------|-----|--|--|-----------------------------------|

**Affidavit:**

N/A

|                   |          |  |      |        |
|-------------------|----------|--|------|--------|
| Timothy Albertson | Approved | Jan-22-2021 16:48:13 (UTC-08:00)<br>Pacific Time (US & Canada) | BOOK | Signed |
|-------------------|----------|--|------|--------|

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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, Signed, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**Affidavit:**

By my dated signature below, I, TimothyAlbertson, 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.

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT SELECTION - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Protocol version*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-28-2020<br>08:52:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>06 OCT 2020 | Initial Entry |

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

| Date  | Location        | User                | Value                                 | Reason        |
|---|-----------------|---------------------|---------------------------------------|---------------|
| Oct-28-2020<br>08:52:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>STAGE 3 COHORTS | Initial Entry |



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Consent Was:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-29-2020<br>08:48:32<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consent Obtained<br><br>Oct/27/2020 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:54

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DEMOGRAPHY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Subject ID**

| Date  | Location        | User                    | Value                          | Reason                               |
|---|-----------------|-------------------------|--------------------------------|--------------------------------------|
| Oct-28-2020<br>08:52:08<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>12641229 | Item copied<br>from previous<br>form |

**2. Birth Date:**

| Date  | Location        | User                    | Value                              | Reason              |
|---|-----------------|-------------------------|------------------------------------|---------------------|
| Oct-28-2020<br>08:52:03<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>(b) (6)/1958 | Enrollment<br>Entry |

**3. Sex:**

| Date  | Location        | User   | Value             | Reason                      |
|---|-----------------|--|-------------------|-----------------------------|
| Oct-30-2020<br>01:59:21<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[Redacted]<br>[Redacted] | Query 1: Closed   | Response<br>satisfies query |
| Oct-29-2020<br>08:48:09<br>(UTC-08:00)<br>Pacific Time (US              | ACV0PFEINFP6000 | auto query<br>(autoquery)                    | Query 1: Answered | Initial Entry               |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                     |                            |   |
|---|-----------------|---------------------|----------------------------|---|
| & Canada)   |                 |                     |                            |   |
| Oct-29-2020<br>08:48:09<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>MALE | Initial Entry   |
| Oct-28-2020<br>23:51:15<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Opened            | DM: The response for "Sex,Ethnicity and Race" is missing. Kindly review and update. |

**4. Ethnicity:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-29-2020<br>08:48:09<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>HISPANIC OR LATI<br>NO(A) OR OF SPA<br>NISH ORIGIN | Initial Entry |

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

| Date  | Location        | User                | Value                       | Reason        |
|---|-----------------|---------------------|-----------------------------|---------------|
| Oct-29-2020<br>08:48:09<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>WHITE | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Visit**

| Date  | Location        | User                | Value                             | Reason  |
|---|-----------------|---------------------|-----------------------------------|---|
| Oct-30-2020<br>23:57:15<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Query 1: Closed                   | Response<br>satisfies query   |
| Oct-30-2020<br>12:21:44<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Answered                 | This has been<br>completed.<br>Thank you.   |
| Oct-29-2020<br>06:19:37<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Opened                   | DM: Kindly<br>review and<br>complete 'HIV<br>status, Medical<br>History,<br>Reactogenicity<br>Diary,<br>Vaccination,<br>Randomization,<br>Vital Signs'<br>forms at this<br>visit. Thank<br>you. |
| Oct-28-2020<br>08:53:48<br>(UTC-08:00)<br>Pacific Time (US              | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Oct/27/2020 | Transcription<br>Error  |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                                   |               |
|---|-----------------|---------------------|-----------------------------------|---------------|
| & Canada)   |                 |                     |                                   |               |
| Oct-28-2020<br>08:53:25<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Oct/23/2020 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:52

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Completion/Discontinuation/Death**

| Date   | Location        | User             | Value                             | Reason        |
|--|-----------------|------------------|-----------------------------------|---------------|
| Oct-28-2020<br>08:54:15<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/27/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date   | Location        | User                    | Value                           | Reason        |
|--|-----------------|-------------------------|---------------------------------|---------------|
| Oct-28-2020<br>08:54:15<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENING | Initial Entry |

**3. Status:**

| Date   | Location        | User             | Value                           | Reason        |
|--|-----------------|------------------|---------------------------------|---------------|
| Oct-28-2020<br>08:54:15<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1.a*

| Date   | Location        | User                    | Value   | Reason        |
|--|-----------------|-------------------------|---|---------------|
| Oct-29-2020<br>08:49:26<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Line/MH N 1<br><b>umber:</b><br><b>Medical His</b> Hyperte<br><b>tory Term:</b> nsion<br><b>Start Date:</b> UNK/U<br>NK/201<br>0<br><b>Ongoing:</b> YES | Initial Entry |

*1.a Line/MH Number:*

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-29-2020<br>08:49:26<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

*1.a Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

| Date   | Location        | User                | Value                              | Reason        |
|--|-----------------|---------------------|------------------------------------|---------------|
| Oct-29-2020<br>08:49:26<br>(UTC-08:00)<br>Pacific Time (US | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Hypertension | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

& Canada)

**1.a Start Date:**

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Oct-29-2020<br>08:49:26<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2010 | Initial Entry |

**1.a Ongoing:**

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-29-2020<br>08:49:26<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**1.b**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Oct-29-2020<br>08:50:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH</b> 2<br><b>Number:</b><br><b>Medical H</b> ACL repai<br><b>istory Ter</b> r, left<br><b>m:</b><br><b>Start Date</b> UNK/UN<br><b>:</b> K/1990 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |  |                    |  |
|--|--|--|--------------------|--|
|  |  |  | <b>Ongoing:</b> NO |  |
|  |  |  | End Date           |  |
|  |  |  | :                  |  |
|  |  |  | UNK/U              |  |
|  |  |  | NK/199             |  |
|  |  |  | 0                  |  |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**1.b Line/MH Number:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-29-2020<br>08:50:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>2 | Initial Entry |

**1.b Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date  | Location        | User                | Value                                  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-29-2020<br>08:50:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>ACL repair, left | Initial Entry |

**1.b Start Date:**

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Oct-29-2020<br>08:50:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/1990 | Initial Entry |

**1.b Ongoing:**

| Date                    | Location        | User    | Value                    | Reason        |
|-------------------------|-----------------|---------|--------------------------|---------------|
| Oct-29-2020<br>08:50:04 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |         |                               |
|--|---------|-------------------------------|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) | (b) (4) | End Date:<br><br>UNK/UNK/1990 |
|--|---------|-------------------------------|

*I.c*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-29-2020<br>08:50:33<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH</b> 3<br><b>Number:</b><br><b>Medical History Term:</b> Meniscus tear repair, left<br><b>Start Date:</b> UNK/UNK/<br>1990<br><b>Ongoing:</b> NO<br>End Date:<br><br>UNK/<br>NK/199<br>0 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***1.c Line/MH Number:***

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-29-2020<br>08:50:33<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>3 | Initial Entry |

***1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-29-2020<br>08:50:33<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Meniscus tear repair,<br>left | Initial Entry |

***1.c Start Date:***

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Oct-29-2020<br>08:50:33<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/1990 | Initial Entry |

***1.c Ongoing:***

| Date                    | Location        | User    | Value                    | Reason        |
|-------------------------|-----------------|---------|--------------------------|---------------|
| Oct-29-2020<br>08:50:33 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |         |                               |
|--|---------|-------------------------------|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) | (b) (4) | End Date:<br><br>UNK/UNK/1990 |
|--|---------|-------------------------------|

*1.d*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-29-2020<br>08:51:01<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH 4</b><br><b>Number:</b><br><b>Medical History Term:</b> Meniscus tear repair, right<br><b>Start Date:</b> UNK/UNK/<br>2016<br><b>Ongoing:</b> NO<br>End Date:<br><br>UNK/UNK/<br>2016 | Initial Entry |

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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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

**1.d Line/MH Number:**

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-29-2020<br>08:51:01<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>4 | Initial Entry |

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-29-2020<br>08:51:01<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Meniscus tear repair,<br>right | Initial Entry |

**1.d Start Date:**

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Oct-29-2020<br>08:51:01<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2016 | Initial Entry |

**1.d Ongoing:**

| Date                    | Location        | User    | Value                    | Reason        |
|-------------------------|-----------------|---------|--------------------------|---------------|
| Oct-29-2020<br>08:51:01 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |         |           |              |
|--|---------|-----------|--------------|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) | (b) (4) | End Date: | UNK/UNK/2016 |
|--|---------|-----------|--------------|

*I.e*

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-29-2020<br>08:51:38<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH N 5</b><br><b>umber:</b><br><b>Medical His Lupus</b><br><b>tory Term:</b><br><b>Start Date:</b> UNK/U<br>NK/201<br>0<br><b>Ongoing:</b> YES | Initial Entry |

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**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

***1.e Line/MH Number:***

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Oct-29-2020<br>08:51:38<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>5 | Initial Entry |

***1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date  | Location        | User             | Value             | Reason  |
|---|-----------------|------------------|-------------------|---|
| Oct-30-2020<br>09:51:05<br>(UTC-08:00)<br>Pacific Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed   | Response satisfies query  |
| Oct-29-2020<br>15:02:28<br>(UTC-08:00)<br>Pacific Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | No, the subject reported that they are managing their lupus symptoms without medication.  |
| Oct-29-2020<br>12:34:40<br>(UTC-08:00)<br>Pacific Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened   | ClinQuery: Is subject receiving treatment with immunosuppressive therapy, including cytotoxic agents or systemic corticosteroids for Lupus? |

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**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                             |               |
|---|-----------------|---------------------|-----------------------------|---------------|
| Oct-29-2020<br>08:51:38<br>(UTC-08:00)<br>Pacific Time<br>(US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Lupus | Initial Entry |
|---|-----------------|---------------------|-----------------------------|---------------|

***I.e Start Date:***

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Oct-29-2020<br>08:51:38<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/2010 | Initial Entry |

***I.e Ongoing:***

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-29-2020<br>08:51:38<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

***I.f***

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Oct-29-2020<br>08:51:56<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br><b>Line/MH</b> 6<br><b>Number:</b> | Initial Entry |

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**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <p><b>Medical History Term:</b> Vasectomy</p> <p><b>Start Date:</b> UNK/UNK/1991</p> <p><b>Ongoing:</b> NO</p> <p><b>End Date:</b></p> <p>UNK/UNK/1991</p> <p>1</p> |  |
|--|--|--|---|--|

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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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

***1.f Line/MH Number:***

| Date  | Location        | User                    | Value                   | Reason        |
|---|-----------------|-------------------------|-------------------------|---------------|
| Oct-29-2020<br>08:51:56<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>6 | Initial Entry |

***1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

| Date  | Location        | User                | Value                           | Reason        |
|---|-----------------|---------------------|---------------------------------|---------------|
| Oct-29-2020<br>08:51:56<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Vasectomy | Initial Entry |

***1.f Start Date:***

| Date  | Location        | User                | Value                              | Reason        |
|---|-----------------|---------------------|------------------------------------|---------------|
| Oct-29-2020<br>08:51:56<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>UNK/UNK/1991 | Initial Entry |

***1.f Ongoing:***

| Date                    | Location        | User    | Value                    | Reason        |
|-------------------------|-----------------|---------|--------------------------|---------------|
| Oct-29-2020<br>08:51:56 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |         |              |  |
|--|--|---------|--------------|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) | End Date:    |  |
|  |  |         | UNK/UNK/1991 |  |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 15-Sep-2020 21:57

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** HIV STATUS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - What is the subject HIV status?*

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-29-2020<br>08:49:33<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>The subject is NOT known to be HIV POSITIVE | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date:**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/27/2020 | Initial Entry |

**2. Weight:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>97.6 | Initial Entry |

**3. Unit:**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>kg | Initial Entry |

**4. Height:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                             |               |
|---|-----------------|---------------------|-----------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>168.7 | Initial Entry |
|---|-----------------|---------------------|-----------------------------|---------------|

**5. Unit:**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>cm | Initial Entry |

**6. Body Mass Index:**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>34.3 | Initial Entry |

**7.a**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b> 1<br><b>Temperature:</b> 36.3 | Initial Entry |

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**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <b>Temperatur C<br/>e Unit:</b><br><b>Temperatur FORE<br/>e Location::</b> HEAD |  |
|--|--|--|---|--|

**7.a Record Identifier:**

| Date  | Location        | User                | Value                   | Reason        |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

**7.a Temperature:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>36.3 | Initial Entry |

**7.a Unit:**

| Date  | Location        | User                | Value                   | Reason        |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**7.a Temperature Location:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Oct-29-2020<br>08:54:48<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** RANDOMIZATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

[Back to Form](#)

**1. Randomization Date :**

| Date  | Location        | User             | Value                             | Reason        |
|---|-----------------|------------------|-----------------------------------|---------------|
| Oct-30-2020<br>12:21:19<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Oct/27/2020 | Initial Entry |

**2. Randomization Number:**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-30-2020<br>12:21:19<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>273378 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-28-2020<br>08:54:33<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-28-2020<br>08:54:33<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value              | Reason                                    |
|---|-----------------|---------------------------|--------------------|---|
| Oct-28-2020<br>08:54:54<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query                       |
| Oct-28-2020<br>08:54:33<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                  |   |  |
|---|-----------------|------------------|---|--|
| Pacific Time (US & Canada)                                  |                 |                  |   | no barcodes are entered. Please review and correct as appropriate. |
| Oct-28-2020 08:54:33 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Oct/27/2020 | Initial Entry  |

5.a

| Date  | Location        | User             | Value                                   | Reason        |
|---|-----------------|------------------|---|---------------|
| Oct-28-2020 08:54:54 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID: BRSSB7 | Initial Entry |

5.a Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-28-2020 08:54:54 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BRSSB7 | Initial Entry |

5.b

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Oct-28-2020<br>08:55:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID: BRSSB8</b> | Initial Entry |
|---|-----------------|---------------------|--|---------------|

5.b Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-28-2020<br>08:55:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BRSSB8 | Initial Entry |

5.c

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-28-2020<br>08:55:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID BM930</b><br>:<br>W | Initial Entry |

5.c Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-28-2020<br>08:55:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BM930W | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-28-2020<br>08:55:21<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Oct-28-2020<br>08:55:21<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value              | Reason                                    |
|---|-----------------|---------------------------|--------------------|---|
| Oct-28-2020<br>08:55:32<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query                       |
| Oct-28-2020<br>08:55:21<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                  |   |  |
|---|-----------------|------------------|---|--|
| Pacific Time (US & Canada)                                  |                 |                  |   | no barcodes are entered. Please review and correct as appropriate. |
| Oct-28-2020 08:55:21 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Oct/27/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Oct-28-2020 08:55:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BM930V | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Oct-28-2020 08:55:32 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BM930V | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Was there a temporary delay of vaccination?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                     |   |               |
|---|-----------------|---------------------|---|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Oct/27/2020 14:26 | Initial Entry |
|---|-----------------|---------------------|---|---------------|

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**10. Timeframe Subject Was Observed**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPE<br>CIFIED OBSERVATIO<br>N PERIOD | Initial Entry |

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

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Oct-29-2020<br>08:55:36<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V1\_DAY1\_VAX1\_L

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Reactogenicity diary collection*

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Oct-29-2020<br>08:55:44<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO - REACTOGENI<br>CITY E-DIARY NO<br>T COLLECTED FO<br>R THIS SUBJECT | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020<br>12:08:43<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/16/2020 | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 10-Oct-2020 16:01

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date:**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Nov-16-2020<br>12:09:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/16/2020 | Initial Entry |

**2.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Nov-16-2020<br>12:09:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> 1<br><b>Temperature:</b> 36.0<br><b>Temperature Unit:</b><br><b>Temperature Location::</b> HEAD | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User                | Value                   | Reason        |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-16-2020<br>12:09:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:01

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

2.a Temperature:

| Date  | Location        | User                      | Value                      | Reason   |
|---|-----------------|---------------------------|----------------------------|--|
| Nov-17-2020<br>00:11:51<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Closed            | Response<br>satisfies query  |
| Nov-16-2020<br>12:34:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Answered          | Per PI, NCS  |
| Nov-16-2020<br>12:09:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened            | Temperature<br>36 C is outside<br>of Normal<br>Range 36.1 -<br>37.5 C. |
| Nov-16-2020<br>12:09:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>36.0 | Initial Entry  |

2.a Unit:

| Date  | Location        | User                | Value                   | Reason        |
|---|-----------------|---------------------|-------------------------|---------------|
| Nov-16-2020<br>12:09:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>C | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:01

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**2.a Temperature Location:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Nov-16-2020<br>12:09:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FOREHEAD | Initial Entry |

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Nov-16-2020<br>10:54:44<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Nov-16-2020<br>10:54:44<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value              | Reason                                    |
|---|-----------------|---------------------------|--------------------|---|
| Nov-16-2020<br>10:54:53<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query                       |
| Nov-16-2020<br>10:54:44<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                  |   |  |
|---|-----------------|------------------|---|--|
| Pacific Time (US & Canada)                                  |                 |                  |   | no barcodes are entered. Please review and correct as appropriate. |
| Nov-16-2020 10:54:44 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Nov/16/2020 | Initial Entry  |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Nov-16-2020 10:54:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br><b>Sample ID:</b> BM92F5 | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Nov-16-2020 10:54:53 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BM92F5 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Was there a temporary delay of vaccination?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BLINDED THERAPY | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                     |   |               |
|---|-----------------|---------------------|---|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Nov/16/2020 09:52 | Initial Entry |
|---|-----------------|---------------------|---|---------------|

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:04

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**10. Timeframe Subject Was Observed**

| Date  | Location        | User                    | Value   | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>THE PROTOCOL SPE<br>CIFIED OBSERVATIO<br>N 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        |
|---|-----------------|---------------------|---------------------------|---------------|
| Nov-16-2020<br>12:10:12<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

| Date  | Location        | User                | Value             | Reason   |
|---|-----------------|---------------------|-------------------|--|
| Dec-23-2020<br>02:54:20<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | Query 1: Closed   | Response<br>satisfies query  |
| Dec-22-2020<br>08:33:05<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Answered | Changed data<br>per query  |
| Dec-22-2020<br>03:41:47<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | Query 1: Opened   | DM: The<br>treatment<br>period is<br>defined as 1st<br>vaccination<br>visit through<br>the 1-month<br>post<br>vaccination<br>visit after the<br>2nd<br>vaccination.<br>Please<br>complete<br>treatment<br>disposition<br>CRF and<br>update date of |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |                 |                  |                                   |  |
|--|-----------------|------------------|-----------------------------------|--|
|  |                 |                  |                                   | EOT to match date of visit at visit 3. |
| Dec-21-2020<br>08:21:03<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/18/2020 | Initial Entry                          |

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264 **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-21-2020<br>08:21:17<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Dec-21-2020<br>08:21:17<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value              | Reason                                    |
|---|-----------------|---------------------------|--------------------|---|
| Dec-21-2020<br>08:21:27<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query                       |
| Dec-21-2020<br>08:21:17<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Frozen, Verified

Site No: 1264 Site Name: (1264) University of California Davis Health

Subject No: 12641229 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                  |   |  |
|---|-----------------|------------------|---|--|
| Pacific Time (US & Canada)                                  |                 |                  |   | no barcodes are entered. Please review and correct as appropriate. |
| Dec-21-2020 08:21:17 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Dec/18/2020 | Initial Entry  |

5.a

| Date  | Location        | User             | Value                                   | Reason        |
|---|-----------------|------------------|---|---------------|
| Dec-21-2020 08:21:27 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID: BM92JJ | Initial Entry |

5.a Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Dec-21-2020 08:21:27 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BM92JJ | Initial Entry |

5.b

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03 Form Status: Data Complete, Frozen, Verified

Site No: 1264 Site Name: (1264) University of California Davis Health

Subject No: 12641229 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Dec-21-2020<br>08:21:37<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID: BSGR11</b> | Initial Entry |
|---|-----------------|---------------------|--|---------------|

5.b Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-21-2020<br>08:21:37<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BSGR11 | Initial Entry |

5.c

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-21-2020<br>08:21:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID: BSGR12</b> | Initial Entry |

5.c Sample ID

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-21-2020<br>08:21:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BSGR12 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

| Date  | Location        | User                      | Value             | Reason   |
|---|-----------------|---------------------------|-------------------|--|
| Dec-15-2020<br>21:21:49<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed   | As per site<br>confirmation -<br>updated PD<br>tracker   |
| Dec-15-2020<br>09:09:13<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Answered | Data entered is<br>accurate.   |
| Dec-15-2020<br>04:19:02<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Opened   | PDQ : Details<br>of Sample ID<br>(barcode) and<br>collection date<br>for either Nasal<br>Swab Self or<br>Nasal Swab<br>expected to be<br>completed.<br>Please check<br>and update else<br>clarify. |
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US              | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Deleted  | Close Auto<br>Query  |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                           |                                   |  |
|---|-----------------|---------------------------|-----------------------------------|--|
| & Canada)   |                 |                           |                                   |  |
| Dec-14-2020<br>09:00:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 2: Candidate                | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.          |
| Dec-14-2020<br>09:00:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate                | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Dec-14-2020<br>09:00:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry  |

**3. COVID-19 Illness Visit:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                         |                               |               |
|---|-----------------|-------------------------|-------------------------------|---------------|
| Dec-14-2020<br>09:00:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>COVID_A | Initial Entry |
|---|-----------------|-------------------------|-------------------------------|---------------|

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Assessment:**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/10/2020 | Initial Entry |

**2. Date of First Symptom Started:**

| Date  | Location        | User                | Value                            | Reason        |
|---|-----------------|---------------------|----------------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/7/2020 | Initial Entry |

**3. Symptoms Ongoing?**

| Date  | Location        | User                      | Value             | Reason                      |
|---|-----------------|---------------------------|-------------------|-----------------------------|
| Jan-20-2021<br>05:22:47<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | Query 1: Closed   | Response<br>satisfies query |
| Jan-19-2021<br>14:35:57<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Answered | New<br>Information          |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |                 |                     |   |   |
|--|-----------------|---------------------|---|---|
| Pacific Time (US & Canada)   |                 |                     |   |   |
| Jan-19-2021<br>14:35:57<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO<br>Date of Last Symptom Resolved:<br><br>Dec/15/2020 | New Information   |
| Jan-19-2021<br>07:23:45<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | Query 1: Opened   | CLINQUERY:<br>Please clarify whether the reported symptoms are still ongoing? If symptoms have ended, please update 'Symptoms Ongoing' on to 'NO' and add Date of Last Symptom Resolved on the CRF. |
| Dec-18-2020<br>15:16:36<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>YES   | New Information   |
| Dec-14-2020<br>09:02:18  | ACV0PFEINFP6000 | (b) (6)             | <b>Data Entry:</b><br>NO  | Initial Entry   |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |         |  |
|--|---------|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) | (b) (4) | Date of Last Symptom Resolved:<br><br>Dec/8/2020 |
|--|---------|--|

**4.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> FEV<br>ER<br><b>Symptom Present:</b> NO | Initial Entry |

**4.a Symptoms:**

| Date  | Location        | User                | Value                       | Reason        |
|---|-----------------|---------------------|-----------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>FEVER | Initial Entry |

**4.a Was symptom present?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**4.b**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sympt</b> NEW OR I<br><b>oms:</b> NCREASE<br>D COUGH<br><br><b>Sympt</b> NO<br><b>om Pre</b><br><b>sent:</b> | Initial Entry |

**4.b Symptoms:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREAS<br>ED COUGH | Initial Entry |

**4.b Was symptom present?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.c**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |   |               |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symp NEW OR IN</b><br><b>toms: CREAS S</b><br><b>HORTNESS</b><br><b>OF BREATH</b><br><br><b>Symp YES</b><br><b>tom</b><br><b>Prese</b><br><b>nt:</b> | Initial Entry |
|---|-----------------|---------------------|---|---------------|

**4.c Symptoms:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREAS<br>ED SHORTNESS O<br>F BREATH | Initial Entry |

**4.c Was symptom present?**

| Date  | Location        | User                | Value                     | Reason        |
|---|-----------------|---------------------|---------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**4.d**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> CHIL<br>LS<br><b>Symptom Pr NO<br/>esent:</b> | Initial Entry |
|---|-----------------|---------------------|--|---------------|

**4.d Symptoms:**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>CHILLS | Initial Entry |

**4.d Was symptom present?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.e**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sympt NEW OR IN<br/>oms:</b> CREASED<br>MUSCLE P<br>AIN | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |  |                         |  |
|--|--|--|-------------------------|--|
|  |  |  | <b>Symptom Present:</b> |  |
|--|--|--|-------------------------|--|

**4.e Symptoms:**

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED MUSCLE PAIN | Initial Entry |

**4.e Was symptom present?**

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.f**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL<br><b>Symptom Present:</b> NO | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**4.f Symptoms:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW LOSS OF TASTE OR SMELL | Initial Entry |

**4.f Was symptom present?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.g**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symp</b> NEW OR IN<br><b>toms:</b> CREASED<br>SORE THROAT<br><b>Symp</b> NO<br><b>tom Present</b><br>: | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**4.g Symptoms:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NEW OR INCREASED SORE THROAT | Initial Entry |

**4.g Was symptom present?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.h**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms:</b> DIARR<br>HEA<br><b>Symptom NO</b><br><b>Present:</b> | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**4.h Symptoms:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>DIARRHEA | Initial Entry |

**4.h Was symptom present?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**4.i**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms</b> VOMI<br>:<br>TING<br><b>Symptom</b> NO<br><b>Present:</b> | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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

**Form Version:** 10-Dec-2020 02:29

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**4.i Symptoms:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>VOMITING | Initial Entry |

**4.i Was symptom present?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:02:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**5.a**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:02:33<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Symptoms -</b> Fatig<br><b>Other:</b> ue | Initial Entry |

**5.a Symptoms - Other Text:**

| Date                    | Location        | User    | Value                         | Reason        |
|-------------------------|-----------------|---------|-------------------------------|---------------|
| Dec-14-2020<br>09:02:33 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Fatigue | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Dec-2020 02:29

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |         |  |  |
|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Actual Date of Collection:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Specimen Type:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Specimen Collection Location:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Assay Code and Description:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                                |               |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

**5. Device Type:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**6. Trade Name:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**7. Test Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:54

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**8. Comments/Findings/Details:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**9. Trade Name Other, Specify:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:02:40<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-14-2020<br>09:03:10<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                                 | Reason        |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Dec-14-2020<br>09:03:10<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB_SELF | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value           | Reason                                    |
|---|-----------------|---------------------------|-----------------|---|
| Dec-21-2020<br>08:53:20<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed | Close Auto<br>Query                       |
| Dec-21-2020<br>02:08:19<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                        |                    |   |
|---|-----------------|------------------------|--------------------|---|
| Pacific Time (US & Canada)                                  |                 |                        |                    | no barcodes are entered. Please review and correct as appropriate.  |
| Dec-18-2020 15:16:36 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed    | Close Auto Query  |
| Dec-18-2020 15:01:47 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened    | Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate. |
| Dec-18-2020 15:01:47 (UTC-08:00) Pacific 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.  |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |   |                    |
|---|-----------------|---------------------|---|--------------------|
| Dec-18-2020<br>15:01:47<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)    | <b>Data Entry:</b><br>YES<br>Date of Collection<br>:<br><br>Dec/17/2020 | New<br>Information |
| Dec-14-2020<br>09:03:10<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO  | Initial Entry      |

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

| Date  | Location        | User                      | Value  | Reason                      |
|---|-----------------|---------------------------|--|-----------------------------|
| Dec-18-2020<br>15:20:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>Subject was currentl<br>y traveling and did<br>not bring his swab k<br>it, swab could not b<br>e collected until his<br>return home and dis<br>charge from hospital<br>. | Initial Entry               |
| Dec-18-2020<br>15:19:51<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed  | Close Auto<br>Query         |
| Dec-18-2020<br>15:19:51   | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b>   | in response to<br>technical |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                           |  |  |
|---|-----------------|---------------------------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada)                            |                 |                           |  | query<br>regarding error<br>in data field<br>concerning<br>extra spaces.   |
| Dec-18-2020<br>15:17:55<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened  | Entered text<br>has either a<br>carriage return<br>(line break) or<br>extra spaces at<br>the end of the<br>text or<br>between<br>words. Please<br>correct by<br>removing all<br>data in the<br>field and<br>re-enter<br>without adding<br>extra spaces or<br>using enter or<br>tab keys. |
| Dec-18-2020<br>15:17:55<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>Subject was currentl<br>y traveling and did<br>not bring his swab k<br>it, swab could not b<br>e collected until his<br>return home and dis<br>charge from hospital<br>. | New<br>Information   |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |   |               |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:03:10<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Subject is currently<br>traveling and did no<br>t bring his swab kit. | Initial Entry |
|---|-----------------|---------------------|---|---------------|

**5.a**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-21-2020<br>08:53:20<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID</b> RR0246<br>:<br>0 | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User                | Value                         | Reason        |
|---|-----------------|---------------------|-------------------------------|---------------|
| Dec-21-2020<br>08:53:20<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>RR02460 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Dec-14-2020<br>09:03:37<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Dec-14-2020<br>09:03:37<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:03:37<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

| Date  | Location        | User                      | Value  | Reason   |
|---|-----------------|---------------------------|--|--|
| Dec-18-2020<br>15:31:19<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | <b>Data Entry:</b><br>Subject was out of the country and subsequently hospitalized, and swab could not be collected until 17Dec20. | New Information  |
| Dec-14-2020<br>09:05:24<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed  | Close Auto Query   |
| Dec-14-2020<br>09:05:24<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)       | <b>Data Entry:</b><br>Subject is currently traveling out of the country, unable to collect swab.                                   | Transcription Error  |
| Dec-14-2020<br>09:03:37<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Opened  | Entered text has either a carriage return (line break) or extra spaces at the end of the text or between words. Please correct by removing all data in the field and re-enter without adding |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |                 |                     |  |  |
|--|-----------------|---------------------|--|--|
|  |                 |                     |  | extra spaces or using enter or tab keys. |
| Dec-14-2020<br>09:03:37<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Subject is currently traveling out of the country, unable to collect swab. | Initial Entry                            |

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020**Form Version:** 10-Dec-2020 02:26**Site No:** 1264**Subject No:** 12641229**Generated By:** (b) (4)**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History**Form Status:** Data Complete**Site Name:** (1264) University of California Davis Health**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 18:51[Back to Form](#)*I.a*

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Prac</b> SPEC<br><b>titioner:</b> IALI<br>ST<br><b>Occurrence</b> NO<br><b>of Visits or C</b><br><b>ontacts:</b> | Initial Entry |

*I.a Physician or Healthcare Professional:*

| Date  | Location        | User                | Value                            | Reason        |
|---|-----------------|---------------------|----------------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>SPECIALIST | Initial Entry |

*I.a Occurrence of Visits or Contacts:*

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

***1.b***

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Pr</b> EMER<br><b>actioner:</b> GENC<br>Y ROO<br>M<br><b>Occurrence of Visits or Contact</b> NO<br><b>s:</b> | Initial Entry |

***1.b Physician or Healthcare Professional:***

| Date  | Location        | User                | Value                                    | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>EMERGENCY ROO<br>M | Initial Entry |

***1.b Occurrence of Visits or Contacts:***

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.c***

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

Form: HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of P</b> PRIMAR<br><b>ractitione</b> Y CARE<br><b>r:</b> PHYSICI<br>AN<br><b>Occurren</b> NO<br><b>ce of Visi</b><br><b>ts or Con</b><br><b>tacts:</b> | Initial Entry |

*1.c Physician or Healthcare Professional:*

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>PRIMARY CARE P<br>HYSICIAN | Initial Entry |

*1.c Occurrence of Visits or Contacts:*

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*1.d*

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |   |               |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> URGENT CARE<br><b>Occurrence of Visits or Contacts:</b> NO | Initial Entry |
|---|-----------------|---------------------|---|---------------|

***1.d Physician or Healthcare Professional:***

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>URGENT CARE | Initial Entry |

***1.d Occurrence of Visits or Contacts:***

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

***1.e***

| Date                                   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Type of Practitioner:</b> TELEPHONE ONE CO | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|                            |                  |                   |  |
|----------------------------|------------------|-------------------|--|
| Pacific Time (US & Canada) | (b) (4), (b) (6) | r: NSULTA<br>TION | Occurren NO<br>ce of Visi<br>ts or Con<br>tacts: |
|----------------------------|------------------|-------------------|--|

*I.e Physician or Healthcare Professional:*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>TELEPHONE CONS<br>ULTATION | Initial Entry |

*I.e Occurrence of Visits or Contacts:*

| Date   | Location        | User                | Value                    | Reason        |
|--|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

*I.f*

| Date   | Location        | User                | Value  | Reason        |
|--|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Type of Practi OT<br>tioner: HE<br>R | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Version:** 10-Dec-2020 02:26

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|           |  |  |  |  |
|-----------|--|--|--|--|
| & Canada) |  |  | <b>Occurrence of NO<br/>Visits or Cont<br/>acts:</b> |  |
|-----------|--|--|--|--|

***1.f Physician or Healthcare Professional:***

| <b>Date</b>   | <b>Location</b> | <b>User</b>         | <b>Value</b>                | <b>Reason</b> |
|---|-----------------|---------------------|-----------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>OTHER | Initial Entry |

***1.f Occurrence of Visits or Contacts:***

| <b>Date</b>   | <b>Location</b> | <b>User</b>         | <b>Value</b>             | <b>Reason</b> |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

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

| <b>Date</b>   | <b>Location</b> | <b>User</b>         | <b>Value</b>             | <b>Reason</b> |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:03:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 06-Jul-2020 21:53

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail  
History

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. What is the treatment Identifier?**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:04:02<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Concomitant Non-drug Treatment Pre-specified:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:04:02<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Treatment:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:04:02<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Treatment:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail  
History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                                |               |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:04:02<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

**5. Start Date:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:04:02<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**6. Ongoing?**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:04:02<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Category of Clinical Event:**

| Date  | Location        | User                    | Value  | Reason        |
|---|-----------------|-------------------------|--|---------------|
| Dec-14-2020<br>09:05:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>POTENTIAL COVID-<br>19 ILLNESS | Initial Entry |

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Dec-14-2020<br>09:05:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**3. Toxicity Grade:**

| Date  | Location        | User                | Value                   | Reason        |
|---|-----------------|---------------------|-------------------------|---------------|
| Dec-14-2020<br>09:05:52<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>1 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit  
Trail History

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Category of Clinical Event:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:22:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Subcategory of Clinical Event:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:22:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Was a diagnosis obtained?**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:22:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Toxicity Grade:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit  
Trail History

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                                |               |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:22:45<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Lab Panel:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Laboratory Name and Address**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Specimen Type:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                                |               |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

**5.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

**5.a Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a Test:**

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

Form: LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a Not Done:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a LNMT**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

& Canada)

**5.b**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier</b> Not Done<br><b>Test::</b> Not Done<br><b>Result::</b> Not Done<br><b>Not Done::</b> Not Done<br><b>Lab Normal Range:</b> Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.b Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.b Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.b Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.b Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |         |  |  |
|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.b LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.c**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.c Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.c Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.c Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.c Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |         |  |  |
|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.c LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.d**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.d Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.d Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.d Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.d Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |         |  |  |
|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.d LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.e**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Oct-2020 15:58

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.e Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.e Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.e Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.e Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00)  
Pacific Time (US  
& Canada)

(b) (4)

**5.e LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.f**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.f Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.f Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.f Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.f Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.f LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.g**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.g Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.g Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.g Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.g Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Version:** 10-Oct-2020 15:58

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |         |  |  |
|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.g LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:06<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Lab Panel:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Laboratory Name and Address**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Collection Date:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Specimen Type:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                                |               |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

**5.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

**5.a Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a Test:**

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a Not Done:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.a LNMT**

| Date   | Location        | User                | Value                          | Reason        |
|--|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

& Canada)

**5.b**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defined Identifier</b> Not Done<br><b>Test::</b> Not Done<br><b>Result::</b> Not Done<br><b>Not Done::</b> Not Done<br><b>Lab Normal Range:</b> Not Done | Initial Entry |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.b Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.b Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.b Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.b Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.b LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.c**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

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Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.c Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.c Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.c Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.c Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

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|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.c LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.d**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form Version:** 10-Oct-2020 16:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.d Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.d Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.d Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.d Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

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**Generated By:** (b) (4)

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(UTC-08:00)  
Pacific Time (US  
& Canada)

(b) (4)

**5.d LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.e**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.e Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.e Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.e Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.e Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00)  
Pacific Time (US  
& Canada)

(b) (4)

**5.e LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.f**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.f Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.f Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.f Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.f Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.f LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.g**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.g Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.g Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.g Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.g Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |         |  |  |
|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.g LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.h**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 10-Oct-2020 16:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.h Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.h Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.h Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.h Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00)  
Pacific Time (US  
& Canada)

(b) (4)

**5.h LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**5.i Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.i Not Done:**

| Date | Location | User | Value | Reason |
|------|----------|------|-------|--------|
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090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                                |               |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

**5.i LNMT**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Sponsor-Defi</b> Not<br><b>ned Identifier</b> Done<br>:<br><b>Test::</b> Not<br>Done<br><b>Result::</b> Not<br>Done<br><b>Not Done::</b> Not<br>Done<br><b>Lab Normal</b> Not<br><b>Range:</b> Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form Version:** 10-Oct-2020 16:02

**Site No:** 1264

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**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

**5.j Sponsor ID:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j Test:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j Result:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**5.j Not Done:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 10-Oct-2020 16:02

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |         |  |  |
|--|--|---------|--|--|
| (UTC-08:00)<br>Pacific Time (US<br>& Canada) |  | (b) (4) |  |  |
|--|--|---------|--|--|

**5.j LNMT**

| <b>Date</b>   | <b>Location</b> | <b>User</b>         | <b>Value</b>                   | <b>Reason</b> |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:43<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2.a**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Dec-14-2020<br>09:06:43<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier::</b> Not Done<br><b>Systolic::</b> Not Done<br><b>Diastolic::</b> Not Done<br><b>Respiratory Rate in respirations/minute:</b> Not Done<br><b>Heart Rate in beats/minute:</b> Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**2.a Record Identifier:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:43<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2.a Systolic:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:43<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2.a Diastolic:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:43<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2.a Respiratory Rate in respirations/minute:**

| Date                    | Location        | User    | Value                          | Reason        |
|-------------------------|-----------------|---------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:43 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 10-Oct-2020 15:59

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00)  
Pacific Time (US  
& Canada)

(b) (4)

**2.a Heart Rate in beats/minute:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:43<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:54<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2.a**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Dec-14-2020<br>09:06:54<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br><b>Record Identifier:</b> Not Done<br><b>Oxygen Saturation:</b> Not Done | Initial Entry |

**2.a Record Identifier:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:54<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2.a SPO2 Pulse Oximetry %**

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 10-Oct-2020 16:04

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:06:54<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** OXYGENATION PARAMETERS - eCRF Audit  
Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date Time of Assessment:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:07:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Arterial Blood Gases PaO2 (mmHg):**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:07:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. FiO2 (Fraction of Inhaled Oxygen):**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:07:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - eCRF Audit Trail History

**Form Status:** Data Complete

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. What is the medication identifier?**

| Date  | Location        | User                | Value                                | Reason        |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Dec-14-2020<br>09:22:13<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**2. Category:**

| Date  | Location        | User                | Value                                | Reason        |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Dec-14-2020<br>09:22:13<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**3. Concomitant Medications Pre-specified:**

| Date  | Location        | User                | Value                                | Reason        |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Dec-14-2020<br>09:22:13<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic*

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

*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        |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Dec-14-2020<br>09:22:13<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**5. Start Date:**

| Date  | Location        | User                | Value                                | Reason        |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Dec-14-2020<br>09:22:13<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

**6. Ongoing?**

| Date  | Location        | User                | Value                                | Reason        |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Dec-14-2020<br>09:22:13<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Applicable | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Assessment:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:22:31<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**2. Location of Assessment:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:22:31<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**3. Type of Imaging Exam:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:22:31<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |

**4. Assessment:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/10/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |                                |               |
|---|-----------------|---------------------|--------------------------------|---------------|
| Dec-14-2020<br>09:22:31<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/14/2021

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Visit**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-14-2021<br>14:55:19<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/14/2021 | Initial Entry |

**3. COVID-19 Illness Visit:**

| Date  | Location        | User                | Value                          | Reason        |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-14-2021<br>14:55:19<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>COVID_A1 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/14/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-14-2021<br>14:55:29<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-14-2021<br>14:55:29<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value              | Reason                                    |
|---|-----------------|---------------------------|--------------------|---|
| Jan-14-2021<br>14:55:41<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query                       |
| Jan-14-2021<br>14:55:29<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/14/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                  |   |  |
|---|-----------------|------------------|---|--|
| Pacific Time (US & Canada)                                  |                 |                  |   | no barcodes are entered. Please review and correct as appropriate. |
| Jan-14-2021 14:55:29 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Jan/14/2021 | Initial Entry  |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Jan-14-2021 14:55:41 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID BM92M<br>: 2 | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-14-2021 14:55:41 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BM92M2 | Initial Entry |

**5.b**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/14/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

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

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Jan-14-2021<br>14:55:55<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID:</b> BSGR2Z | Initial Entry |
|---|-----------------|---------------------|--|---------------|

**5.b Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-14-2021<br>14:55:55<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BSGR2Z | Initial Entry |

**5.c**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Jan-14-2021<br>14:56:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID:</b> BSGR30 | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-14-2021<br>14:56:04<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BSGR30 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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| Date  | Location        | User                           | Value        | Reason |
|---|-----------------|--------------------------------|--------------|--------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US &<br>Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)<br>[REDACTED] | Form Created |        |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

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**1. Category:**

| Date   | Location        | User                    | Value                               | Reason        |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ADVERSE EVENT | Initial Entry |

**2. AE ID:**

| Date   | Location        | User                    | Value                   | Reason        |
|--|-----------------|-------------------------|-------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>1 | Initial Entry |

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

| Date   | Location        | User             | Value                                    | Reason        |
|--|-----------------|------------------|--|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Pulmonary embolism | Initial Entry |

**4. Start Date Time:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                  |  |               |
|---|-----------------|------------------|--|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Dec/7/2020 UNK:UN<br>K | Initial Entry |
|---|-----------------|------------------|--|---------------|

**5. Is the adverse event still ongoing?**

| Date  | Location        | User             | Value                     | Reason        |
|---|-----------------|------------------|---------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

**6. Toxicity Grade:**

| Date  | Location        | User             | Value                   | Reason        |
|---|-----------------|------------------|-------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>4 | Initial Entry |

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

| Date   | Location        | User                   | Value  | Reason   |
|--|-----------------|------------------------|--|--|
| Dec-22-2020<br>05:51:30<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)       | Query 1: Deleted   | Query is invalid or does not apply   |
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate   | For AE Pulmonary embolism: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank. |
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)       | <p><b>Data Entry:</b></p> <p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> | Initial Entry  |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |  |  |   |  |
|--|--|--|---|--|
|  |  |  | <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p> |  |
|--|--|--|---|--|

**8. Is this adverse event the result of a study Medication Error?**  
**If Yes, record the type of medication error on the Medication Error Log.**

| Date   | Location        | User             | Value                    | Reason        |
|--|-----------------|------------------|--------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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

Site No: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

9. Is this event related to study treatment:

| Date   | Location        | User             | Value   | Reason        |
|--|-----------------|------------------|---|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT RELATED<br>If Not Related to study treatment(s), this event is due to:<br><br>OTHER<br><br><i>If Other, specify:</i><br><br>Not specified | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date   | Location        | User             | Value                                | Reason        |
|--|-----------------|------------------|--------------------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NOT APPLICABLE | Initial Entry |

11. Was a Concomitant Medication given?

| Date   | Location        | User             | Value                     | Reason        |
|--|-----------------|------------------|---------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

**12. Was a Non-Drug Treatment given?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**13. What was the outcome of this adverse event?:**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>RECOVERING/RES<br>OLVING | Initial Entry |

**14. Did the adverse event cause the subject to be discontinued from the study?**

| Date  | Location        | User             | Value                    | Reason        |
|---|-----------------|------------------|--------------------------|---------------|
| Dec-17-2020<br>10:19:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**15. Serious Adverse Event Number: For Pfizer Use Only**

| Date                    | Location        | User    | Value                            | Reason        |
|-------------------------|-----------------|---------|----------------------------------|---------------|
| Jan-06-2021<br>05:46:06 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>2020497627 | Initial Entry |

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**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

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00)  
Pacific Time (US  
& Canada)

(b) (4)

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:29 **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Completion/Discontinuation/Death :**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Dec-22-2020<br>08:33:23<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Dec/18/2020 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                             | Reason        |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-22-2020<br>08:33:23<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>VACCINATION | Initial Entry |

**3. Status:**

| Date  | Location        | User                | Value                           | Reason        |
|---|-----------------|---------------------|---------------------------------|---------------|
| Dec-22-2020<br>08:33:23<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264      **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-28-2021<br>08:58:08<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

**Site No:** 1264 **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

| Date  | Location        | User                      | Value                  | Reason   |
|---|-----------------|---------------------------|------------------------|--|
| Feb-04-2021<br>11:49:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Closed        | Close Auto<br>Query  |
| Jan-28-2021<br>19:08:27<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6)          | Query 1: Opened        | The response<br>indicates<br>participant was<br>unblinded,<br>however the<br>TREATMENT<br>UNBLINDED<br>date is missing<br>in the DISP<br>visit. Please<br>complete this<br>date. |
| Jan-28-2021<br>08:58:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidat<br>e | The response<br>indicates<br>participant was<br>unblinded,<br>however the<br>TREATMENT<br>UNBLINDED<br>date is missing<br>in the DISP<br>visit. Please                           |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

**Site No:** 1264 **Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                     |   | complete this date. |
|---|-----------------|---------------------|---|---------------------|
| Jan-28-2021<br>08:58:18<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Participant is willi<br>ng to return for Va<br>ccination 3<br>Participant is:<br><br>eligible per loc<br>al/national reco<br>mmendations a<br>nd confirmed t<br>o have received<br>only placebo at<br>Vaccination 1/2 | Initial Entry       |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date Treatment Unblinded :**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-04-2021<br>11:49:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry |

**2. Primary Reason for Unblinding:**

| Date  | Location        | User                | Value   | Reason        |
|---|-----------------|---------------------|---|---------------|
| Feb-04-2021<br>11:49:28<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>ASSESS ELIGIBILIT<br>Y FOR ADDITIONA<br>L VACCINATION | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

| Date   | Location        | User             | Value                             | Reason   |
|--|-----------------|------------------|-----------------------------------|--|
| Feb-01-2021<br>03:49:26<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed                   | Response satisfies query   |
| Jan-29-2021<br>11:47:54<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered                 | Changed data per query   |
| Jan-29-2021<br>04:25:45<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened                   | DM: Kindly consider to update missing REVAX IE and VACIN TRT forms or else clarify. Thank you. |
| Jan-28-2021<br>08:58:32<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry  |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)



**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Consent Was:**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Jan-28-2021<br>08:58:41<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>OBTAINED<br>Date Written Consen<br>t Obtained<br><br>Jan/27/2021 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Date of Completion/Discontinuation/Death :**

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-28-2021<br>08:58:56<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>Jan/27/2021 | Initial Entry |

**2. Phase of Disposition:**

| Date  | Location        | User                    | Value                                       | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Jan-28-2021<br>08:58:56<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>REPEAT SCREENING<br>1 | Initial Entry |

**3. Status:**

| Date  | Location        | User                | Value                           | Reason        |
|---|-----------------|---------------------|---------------------------------|---------------|
| Jan-28-2021<br>08:58:56<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>COMPLETED | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-28-2021<br>09:03:00<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                       | Reason        |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Jan-28-2021<br>09:03:00<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SERUM | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value              | Reason                                    |
|---|-----------------|---------------------------|--------------------|---|
| Jan-28-2021<br>09:03:13<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query                       |
| Jan-28-2021<br>09:03:00<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                  |   |  |
|---|-----------------|------------------|---|--|
| Pacific Time (US & Canada)                                  |                 |                  |   | no barcodes are entered. Please review and correct as appropriate. |
| Jan-28-2021 09:03:00 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Jan/27/2021 | Initial Entry  |

5.a

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Jan-28-2021 09:03:13 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID BM92M<br>: F | Initial Entry |

5.a Sample ID

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-28-2021 09:03:13 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BM92MF | Initial Entry |

5.b

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                     |  |               |
|---|-----------------|---------------------|--|---------------|
| Jan-28-2021<br>09:03:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID: BSGR5T</b> | Initial Entry |
|---|-----------------|---------------------|--|---------------|

**5.b Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-28-2021<br>09:03:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BSGR5T | Initial Entry |

**5.c**

| Date  | Location        | User                | Value  | Reason        |
|---|-----------------|---------------------|--|---------------|
| Jan-28-2021<br>09:03:29<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br><b>Sample ID BSGR5</b><br>:<br>V | Initial Entry |

**5.c Sample ID**

| Date  | Location        | User                | Value                        | Reason        |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-28-2021<br>09:03:29<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6) | <b>Data Entry:</b><br>BSGR5V | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-28-2021<br>09:03:39<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-28-2021<br>09:03:39<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value              | Reason                                    |
|---|-----------------|---------------------------|--------------------|---|
| Jan-28-2021<br>09:03:51<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query                       |
| Jan-28-2021<br>09:03:39<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|   |                 |                  |   |  |
|---|-----------------|------------------|---|--|
| Pacific Time (US & Canada)                                  |                 |                  |   | no barcodes are entered. Please review and correct as appropriate. |
| Jan-28-2021 09:03:39 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br>Jan/27/2021 | Initial Entry  |

**5.a**

| Date  | Location        | User             | Value  | Reason        |
|---|-----------------|------------------|--|---------------|
| Jan-28-2021 09:03:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>Sample ID BRFH8<br>: G | Initial Entry |

**5.a Sample ID**

| Date  | Location        | User             | Value                        | Reason        |
|---|-----------------|------------------|------------------------------|---------------|
| Jan-28-2021 09:03:51 (UTC-08:00) Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <b>Data Entry:</b><br>BRFH8G | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Was there a temporary delay of vaccination?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                          | Reason        |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                     |   |               |
|---|-----------------|---------------------|---|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Jan/27/2021 16:12 | Initial Entry |
|---|-----------------|---------------------|---|---------------|

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

8. Actual Dose:

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30.0 | Initial Entry |

9. Unit:

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-29-2021<br>11:48:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>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-29-2021<br>11:48:34 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00)  
Pacific Time (US  
& Canada)

(b) (4)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 22-Apr-2020 21:02

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Date of Visit*

| Date  | Location        | User                | Value                             | Reason        |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-17-2021<br>13:16:34<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Feb/17/2021 | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Data Origin**

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-17-2021<br>13:16:15<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SITE | Initial Entry |

**2. Sample Type**

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-17-2021<br>13:16:15<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>NASAL_SWAB | Initial Entry |

**3. Sample Collected?**

| Date  | Location        | User                      | Value              | Reason                                    |
|---|-----------------|---------------------------|--------------------|---|
| Feb-17-2021<br>13:16:26<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Deleted   | Close Auto<br>Query                       |
| Feb-17-2021<br>13:16:15<br>(UTC-08:00)                                  | ACV0PFEINFP6000 | auto query<br>(autoquery) | Query 1: Candidate | 'Sample<br>Collected?' is<br>Yes, however |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |                 |                     |   |  |
|--|-----------------|---------------------|---|--|
| Pacific Time (US & Canada)   |                 |                     |   | no barcodes are entered. Please review and correct as appropriate. |
| Feb-17-2021<br>13:16:15<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>YES<br>Date of Collection:<br><br>Feb/17/2021 | Initial Entry  |

**5.a**

| Date   | Location        | User                | Value   | Reason        |
|--|-----------------|---------------------|---|---------------|
| Feb-17-2021<br>13:16:26<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Sample ID BR4FB<br>:<br>C | Initial Entry |

**5.a Sample ID**

| Date   | Location        | User                | Value                        | Reason        |
|--|-----------------|---------------------|------------------------------|---------------|
| Feb-17-2021<br>13:16:26<br>(UTC-08:00)<br>Pacific Time (US & Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>BR4FBC | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 10-Dec-2020 02:26

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** VACCINATION - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Was there a temporary delay of vaccination?**

| Date  | Location        | User                | Value                    | Reason        |
|---|-----------------|---------------------|--------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>NO | Initial Entry |

**2. Treatment Name**

| Date  | Location        | User                    | Value                          | Reason        |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>BNT162b2 | Initial Entry |

**3. Formulation:**

| Date  | Location        | User                    | Value                           | Reason        |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INJECTION | Initial Entry |

**4. Dose Date Time:**

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

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

|   |                 |                     |   |               |
|---|-----------------|---------------------|---|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>Feb/17/2021 08:15 | Initial Entry |
|---|-----------------|---------------------|---|---------------|

**5. Anatomical Location:**

| Date  | Location        | User                    | Value                                | Reason        |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>DELTOID MUSCLE | Initial Entry |

**6. Body Side:**

| Date  | Location        | User                | Value                      | Reason        |
|---|-----------------|---------------------|----------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6) | <b>Data Entry:</b><br>LEFT | Initial Entry |

**7. Route:**

| Date  | Location        | User                    | Value                               | Reason        |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>INTRAMUSCULAR | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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: 1264

Site Name: (1264) University of California Davis Health

Subject No: 12641229

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 18:51

8. Actual Dose:

| Date  | Location        | User                    | Value                      | Reason        |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>30.0 | Initial Entry |

9. Unit:

| Date  | Location        | User                    | Value                    | Reason        |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date  | Location        | User                    | Value                            | Reason        |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-18-2021<br>15:11:22<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>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-18-2021<br>15:11:22 | ACV0PFEINFP6000 | (b) (6) | <b>Data Entry:</b><br>YES | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (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:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

(UTC-08:00)  
Pacific Time (US  
& Canada)

(b) (4)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

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**1. Subject Status**

| Date  | Location        | User                    | Value                                     | Reason        |
|---|-----------------|-------------------------|---|---------------|
| Dec-22-2020<br>08:33:23<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>FOLLOW-UP           | Initial Entry |
| Oct-30-2020<br>12:21:19<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>ENROLLED/RANDOMIZED | Initial Entry |
| Oct-28-2020<br>08:54:15<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>SCREENED            | Initial Entry |

**2. Subject Status Date**

| Date   | Location        | User                    | Value                             | Reason        |
|--|-----------------|-------------------------|-----------------------------------|---------------|
| Dec-22-2020<br>08:33:23<br>(UTC-08:00)<br>Pacific Time<br>(US &<br>Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Dec/18/2020 | Initial Entry |
| Dec-18-2020  | ACV0PFEINFP6000 | (b) (6)                 | Query 2:                          | event added   |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |                 |                              |                      |  |
|--|-----------------|------------------------------|----------------------|--|
| 04:10:09<br>(UTC-08:00)<br>Pacific Time<br>(US &<br>Canada)                |                 | (b) (4),<br>(b) (6)          | Closed               |  |
| Dec-17-2020<br>05:46:20<br>(UTC-08:00)<br>Pacific Time<br>(US &<br>Canada) | ACV0PFEINFP6000 | (b) (4), (b)<br>(6)          | Query 2:<br>Opened   | SAE<br>RECON:AER#2020497627<br>pulmonary embolism<br>(onset date:07Dec2020)was<br>reported as serious in<br>Safety database but missing<br>in AE CRF. Please confirm<br>and update CRF. If safety<br>update is required, submit a<br>follow-up SAE Form. |
| Dec-15-2020<br>00:19:44<br>(UTC-08:00)<br>Pacific Time<br>(US &<br>Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 1:<br>Closed   | Response satisfies query   |
| Dec-14-2020<br>09:00:27<br>(UTC-08:00)<br>Pacific Time<br>(US &<br>Canada) | ACV0PFEINFP6000 | (b) (4),<br>(b) (6)          | Query 1:<br>Answered | Updated  |
| Dec-14-2020<br>07:12:34<br>(UTC-08:00)<br>Pacific Time<br>(US &            | ACV0PFEINFP6000 | Saumitra<br>Dubey<br>(b) (4) | Query 1:<br>Opened   | Illness ed diary: As per<br>Illness ed diary records,<br>subject reported "Yes" for<br>the question "Have you<br>experienced any of the  |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Verified

**Site No:** 1264

**Site Name:** (1264) University of California Davis Health

**Subject No:** 12641229

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 18:51

|  |                 |                         |                                       |  |
|--|-----------------|-------------------------|---------------------------------------|--|
| Canada)  |                 |                         |                                       | following?" for the COVID-19 symptoms or diagnosis on 08DEC2020. But corresponding COVID Illness visit not reported. Please clarify. |
| Oct-30-2020<br>12:21:19<br>(UTC-08:00)<br>Pacific Time<br>(US &<br>Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/27/20<br>20 | Initial Entry  |
| Oct-28-2020<br>08:54:15<br>(UTC-08:00)<br>Pacific Time<br>(US &<br>Canada) | ACV0PFEINFP6000 | auto calc<br>(autocalc) | <b>Data Entry:</b><br>Oct/27/20<br>20 | Initial Entry  |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1264

**Subject No:** 12641229

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Signed, Verified

**Site Name:** (1264) University of California Davis Health

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 18:51

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*1. Casebook Signature*

| Date  | Location        | User                            | Value  | Reason        |
|---|-----------------|---------------------------------|--|---------------|
| Jan-22-2021<br>16:47:53<br>(UTC-08:00)<br>Pacific Time (US<br>& Canada) | ACV0PFEINFP6000 | Timothy<br>Albertson<br>(b) (4) | <b>Data Entry:</b><br>Click Here to Enabl<br>e | Initial Entry |

090177e196ae3007\Final\Final On: 01-Apr-2021 03:57 (GMT)