

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Cohort Selection

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

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Informed Consent

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [11471230] |
| 2. | Birth Date: | (b) (6)/1961 |
| 3. | Sex: | FEMALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Screening

| | | |
|----|--|------------|
| 1. | Date of Completion/Discontinuation/Death | Sep/9/2020 |
| 2. | Phase of Disposition: | SCREENING |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Medical History Details

| | | |
|-----|--|-------------------------------------|
| 1.a | Line/MH Number: | [1] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [intractable migraine without aura] |
| | Start Date: | UNK/UNK/2015 |
| | Ongoing: | YES |
| 1.b | Line/MH Number: | [2] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [hypertension] |
| | Start Date: | UNK/UNK/2018 |
| | Ongoing: | YES |
| 1.c | Line/MH Number: | [3] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [GERD] |
| | Start Date: | UNK/UNK/2017 |
| | Ongoing: | YES |
| 1.d | Line/MH Number: | [4] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Mild coronary artery disease] |
| | Start Date: | UNK/UNK/2019 |
| | Ongoing: | YES |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|--|------------------------------------|
| 1.e | Line/MH Number: | [5] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [chronic rhinitis] |
| | Start Date: | UNK/UNK/2011 |
| | Ongoing: | YES |
| 1.f | Line/MH Number: | [6] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [factor V leiden disorder] |
| | Start Date: | UNK/UNK/2014 |
| | Ongoing: | YES |
| 1.g | Line/MH Number: | [7] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Insomnia] |
| | Start Date: | UNK/UNK/2019 |
| | Ongoing: | YES |
| 1.h | Line/MH Number: | [8] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [Degenerative disc disease,lumbar] |
| | Start Date: | UNK/UNK/2000 |
| | Ongoing: | YES |
| 1.i | Line/MH Number: | [9] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [cervical radiculopathy] |
| | Start Date: | UNK/UNK/2000 |
| | Ongoing: | YES |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|--|---------------------------|
| 1.j | Line/MH Number: | [10] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [right foot pain] |
| | Start Date: | UNK/UNK/2017 |
| | Ongoing: | YES |
| 1.k | Line/MH Number: | [11] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [allergic to hydrocodone] |
| | Start Date: | UNK/UNK/2000 |
| | Ongoing: | YES |
| 1.l | Line/MH Number: | [12] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [allergic to oxycodone] |
| | Start Date: | UNK/UNK/2000 |
| | Ongoing: | YES |
| 1.m | Line/MH Number: | [13] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [allergic doxycycline] |
| | Start Date: | UNK/UNK/2018 |
| | Ongoing: | YES |
| 1.n | Line/MH Number: | [14] |
| | Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies: | [menopausal] |
| | Start Date: | UNK/UNK/2001 |
| | Ongoing: | YES |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|------------------|------------|
| 1. | Date: | Sep/9/2020 |
| 2. | Weight: | [226.0] |
| 3. | Unit: | LB |
| 4. | Height: | [64.0] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [38.8] |

Vital Signs Details

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Lab Urinalysis

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

Lab Result

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

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|------------|
| 1. | Randomization Date : | Sep/9/2020 |
| 2. | Randomization Number: | [253202] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Sep/9/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BPLF4V] |
| 5.b | Sample ID | [BPY3DS] |
| 5.c | Sample ID | [BPY3DT] |
| 5.d | Sample ID | [BPY3DV] |
| 5.e | Sample ID | [BPLF4D] |

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Sep/9/2020 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BPY3D6] |
|-----|-----------|----------|

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

eCRF Audit Trail History

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BLINDED THERAPY] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Sep/9/2020 13:39 |
| 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 |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Oct/2/2020 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [98.6] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

eCRF Audit Trail History

Lab Urinalysis

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

Lab Result

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Oct/2/2020 |
| 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 | [BR7XC3] |
|-----|-----------|----------|

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[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/2/2020 09:44 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | RIGHT |
| 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 |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Oct/30/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Oct/30/2020 |
| 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 | [BMNV16] |
| 5.b | Sample ID | [BMNV1G] |
| 5.c | Sample ID | [BR7XM1] |
| 5.d | Sample ID | [BR7XM0] |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/01/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Signs and Symptoms

| | | |
|----|--------------------------------|-------------|
| 1. | Date of Assessment: | Feb/1/2021 |
| 2. | Date of First Symptom Started: | Jan/29/2021 |
| 3. | Symptoms Ongoing? | YES |

Symptoms

| | | |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms: | FEVER |
| | Was symptom present? | YES |
| 4.b | Symptoms: | NEW OR INCREASED COUGH |
| | Was symptom present? | YES |
| 4.c | Symptoms: | NEW OR INCREASED SHORTNESS OF BREATH |
| | Was symptom present? | YES |
| 4.d | Symptoms: | CHILLS |
| | Was symptom present? | YES |
| 4.e | Symptoms: | NEW OR INCREASED MUSCLE PAIN |
| | Was symptom present? | YES |
| 4.f | Symptoms: | NEW LOSS OF TASTE OR SMELL |
| | Was symptom present? | YES |
| 4.g | Symptoms: | NEW OR INCREASED SORE THROAT |
| | Was symptom present? | YES |
| 4.h | Symptoms: | DIARRHEA |
| | Was symptom present? | YES |
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | YES |

Symptoms - Other

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Feb/01/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|------------------|------------------------------|--|----------------------------|---------------------------------|
| 1. | Jan/30/2021 | SWABBED MATERIAL | NASOPHARYNX | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | Repeating Pages |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Feb/01/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Microbiology Specimen

| | | |
|----|-------------------------------|--|
| 1. | Actual Date of Collection: | Jan/30/2021 |
| 2. | Specimen Type: | SWABBED MATERIAL |
| 3. | Specimen Collection Location: | NASOPHARYNX |
| 4. | Assay Code and Description: | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 |
| 5. | Device Type: | SARS-COV-2 DIAGNOSTIC TEST |
| 6. | Trade Name: | OTHER |
| 7. | Test Result: | POSITIVE |
| 8. | Comments/Findings/Details: | [] |
| 9. | Trade Name Other, Specify: | [NALT Unknown] |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB_SELF |
| 3. | Sample Collected? | YES Date of Collection: Feb/22/2021 |
| 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 | [RW89794] |
|-----|-----------|-----------|

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[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: | [Site did not collect swab] |

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Feb/01/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471230**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[eCRF Audit Trail History](#)**Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Hospitalization Category | Hospitalization Term | Admission Date | Ongoing | Form Instance |
|----|--------------------------|----------------------|----------------|---|---------------------------------|
| 1. | HOSPITALIZATION STATUS | HOSPITAL | Feb/2/2021 | NO Discharge Date: Feb/6/2021 | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS
on Feb/01/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Hospitalization Details

| | | |
|----|---------------------------|-------------------------------------|
| 1. | Hospitalization Category: | HOSPITALIZATION STATUS |
| 2. | Hospitalization Term: | HOSPITAL |
| 3. | Admission Date: | Feb/2/2021 |
| 4. | Ongoing? | NO Discharge Date: Feb/6/2021 |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Treatment Identifier | Con Non-Drug Treatments Pre-specified | Treatment | Treatment | Start Date | Form Instance |
|----|----------------------|---------------------------------------|--------------------------|--------------------------|------------|---------------------------------|
| 1. | 1 | YES | HIGH FLOW OXYGEN THERAPY | HIGH FLOW OXYGEN THERAPY | Feb/2/2021 | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Feb/01/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Respiratory Treatment

| | | |
|----|---|-------------------------------|
| 1. | What is the treatment Identifier? | [1] |
| 2. | Concomitant Non-drug Treatment Pre-specified: | YES |
| 3. | Treatment: | HIGH FLOW OXYGEN THERAPY |
| 4. | Treatment: | [HIGH FLOW OXYGEN THERAPY] |
| 5. | Start Date: | Feb/2/2021 |
| 6. | Ongoing? | NO End Date: Feb/6/2021 |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Feb/01/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Illness Details

| | | |
|----|--|--|
| 1. | Category of Clinical Event: | POTENTIAL COVID-19 ILLNESS |
| 2. | Was a diagnosis obtained for Potential COVID-19 Illness? | YES Respiratory Illness Diagnosis: [COVID-19] Date of Diagnosis: Jan/30/2021 |
| 3. | Toxicity Grade: | 2 |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Feb/01/2021

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|---|------------------|---------------|-----------------------------------|---------------------------------|----------------|---------------------------------|
| 1. | CLINICAL CHEMISTRY | St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Feb/2/2021 | BLOOD | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | 329 | C Reactive Protein_PX329 | 5.50 | |
| | | | | | 30 | Alanine Aminotransferase_PX30 | 30 | |
| | | | | | 28 | Aspartate Aminotransferase_PX28 | 44 | |
| | | | | | 35 | Alkaline Phosphatase_PX35 | 80 | |
| | | | | | 21 | Bilirubin_PX21 | 0.6 | |
| | | | | | 47 | Blood Urea Nitrogen_PX47 | 20 | |
| | | | | | 48 | Creatinine_PX48 | 1.11 | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 14-Jan-2021 02:30

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|--|------------------|---------------|-----------------------------------|---------------------------------|----------------|---------------------------------|
| 2. | CLINICAL CHEMISTRY | St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Feb/3/2021 | BLOOD | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | 329 | C Reactive Protein_PX329 | [] | |
| | | | | | 30 | Alanine Aminotransferase_PX30 | 37 | |
| | | | | | 28 | Aspartate Aminotransferase_PX28 | 48 | |
| | | | | | 35 | Alkaline Phosphatase_PX35 | 76 | |
| | | | | | 21 | Bilirubin_PX21 | 0.6 | |
| | | | | | 47 | Blood Urea Nitrogen_PX47 | 25 | |
| | | | | | 48 | Creatinine_PX48 | 1.03 | |
| 3. | CLINICAL CHEMISTRY | St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Feb/4/2021 | BLOOD | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | 329 | C Reactive Protein_PX329 | 2.40 | |
| | | | | | 30 | Alanine Aminotransferase_PX30 | 38 | |
| | | | | | 28 | Aspartate Aminotransferase_PX28 | 47 | |
| | | | | | 35 | Alkaline Phosphatase_PX35 | 66 | |
| | | | | | 21 | Bilirubin_PX21 | 0.5 | |
| | | | | | 47 | Blood Urea Nitrogen_PX47 | 28 | |
| | | | | | 48 | Creatinine_PX48 | 0.86 | |
| 4. | CLINICAL CHEMISTRY | St. Tammany Parish Hospital 1202 S Tyler St Covington, LA | Feb/5/2021 | BLOOD | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | 329 | C Reactive Protein | [] | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 14-Jan-2021 02:30

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Category for Lab Test | Vendor Name | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|---|-----------------------|-------------|------------------|---------------|----------------------------|---------------------------------|---------|---------------|
| | | | | | Sponsor-Defined Identifier | Test: | Result: | |
| | | 70433 | | | | | | |
| | | | | | | _PX329 | | |
| | | | | | 30 | Alanine Aminotransferase_PX30 | 37 | |
| | | | | | 28 | Aspartate Aminotransferase_PX28 | 49 | |
| | | | | | 35 | Alkaline Phosphatase_PX35 | 60 | |
| | | | | | 21 | Bilirubin_PX21 | 0.5 | |
| | | | | | 47 | Blood Urea Nitrogen_PX47 | 29 | |
| | | | | | 48 | Creatinine_PX48 | 0.94 | |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/01/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Lab Chemistry Details

| | | |
|----|-----------------------------|--|
| 1. | Lab Panel: | CLINICAL CHEMISTRY |
| 2. | Laboratory Name and Address | [St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433] |
| 3. | Collection Date: | Feb/2/2021 |
| 4. | Specimen Type: | BLOOD |

Lab Result

| | | |
|-----|-------------|--|
| 5.a | Sponsor ID: | [329] |
| | Test: | C Reactive Protein_PX329 |
| | Result: | [5.50] |
| | Not Done: | |
| | LNMT | Low [0.00] High [0.90] Unit mg/dL |
| 5.b | Sponsor ID: | [30] |
| | Test: | Alanine Aminotransferase_PX30 |
| | Result: | [30] |
| | Not Done: | |
| | LNMT | Low [0] High [35] Unit U/L |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/01/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28] |
| | Test: | Aspartate Aminotransferase_PX28 |
| | Result: | [44] |
| | Not Done: | |
| | LNMT | Low [14] High [36] Unit U/L |
| 5.d | Sponsor ID: | [35] |
| | Test: | Alkaline Phosphatase_PX35 |
| | Result: | [80] |
| | Not Done: | |
| | LNMT | Low [38] High [145] Unit U/L |
| 5.e | Sponsor ID: | [21] |
| | Test: | Bilirubin_PX21 |
| | Result: | [0.6] |
| | Not Done: | |
| | LNMT | Low [0.2] High [1.3] Unit mg/dL |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/01/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|---|
| 5.f | Sponsor ID: | [47] |
| | Test: | Blood Urea Nitrogen_PX47 |
| | Result: | [20] |
| | Not Done: | |
| | LNMT | Low [7] High [18] Unit mg/dL |

| | | |
|-----|-------------|--|
| 5.g | Sponsor ID: | [48] |
| | Test: | Creatinine_PX48 |
| | Result: | [1.11] |
| | Not Done: | |
| | LNMT | Low [0.50] High [1.40] Unit mg/dL |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/01/2021

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Lab Chemistry Details

| | | |
|----|-----------------------------|--|
| 1. | Lab Panel: | CLINICAL CHEMISTRY |
| 2. | Laboratory Name and Address | [St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433] |
| 3. | Collection Date: | Feb/3/2021 |
| 4. | Specimen Type: | BLOOD |

Lab Result

| | | |
|-----|-------------|---|
| 5.a | Sponsor ID: | [329] |
| | Test: | C Reactive Protein_PX329 |
| | Result: | [] |
| | Not Done: | NOT DONE |
| | LNMT | Low [] High [] Unit |
| 5.b | Sponsor ID: | [30] |
| | Test: | Alanine Aminotransferase_PX30 |
| | Result: | [37] |
| | Not Done: | |
| | LNMT | Low [0] High [35] Unit U/L |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/01/2021

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28] |
| | Test: | Aspartate Aminotransferase_PX28 |
| | Result: | [48] |
| | Not Done: | |
| | LNMT | Low [14] High [36] Unit U/L |

| | | |
|-----|-------------|---|
| 5.d | Sponsor ID: | [35] |
| | Test: | Alkaline Phosphatase_PX35 |
| | Result: | [76] |
| | Not Done: | |
| | LNMT | Low [38] High [145] Unit U/L |

| | | |
|-----|-------------|--|
| 5.e | Sponsor ID: | [21] |
| | Test: | Bilirubin_PX21 |
| | Result: | [0.6] |
| | Not Done: | |
| | LNMT | Low [0.2] High [1.3] Unit mg/dL |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/01/2021

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|---|
| 5.f | Sponsor ID: | [47] |
| | Test: | Blood Urea Nitrogen_PX47 |
| | Result: | [25] |
| | Not Done: | |
| | LNMT | Low [7] High [18] Unit mg/dL |

| | | |
|-----|-------------|--|
| 5.g | Sponsor ID: | [48] |
| | Test: | Creatinine_PX48 |
| | Result: | [1.03] |
| | Not Done: | |
| | LNMT | Low [0.50] High [1.40] Unit mg/dL |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/01/2021

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Lab Chemistry Details

| | | |
|----|-----------------------------|--|
| 1. | Lab Panel: | CLINICAL CHEMISTRY |
| 2. | Laboratory Name and Address | [St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433] |
| 3. | Collection Date: | Feb/4/2021 |
| 4. | Specimen Type: | BLOOD |

Lab Result

| | | |
|-----|-------------|--|
| 5.a | Sponsor ID: | [329] |
| | Test: | C Reactive Protein_PX329 |
| | Result: | [2.40] |
| | Not Done: | |
| | LNMT | Low [0.00] High [0.90] Unit mg/dL |
| 5.b | Sponsor ID: | [30] |
| | Test: | Alanine Aminotransferase_PX30 |
| | Result: | [38] |
| | Not Done: | |
| | LNMT | Low [0] High [35] Unit U/L |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
on Feb/01/2021

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28] |
| | Test: | Aspartate Aminotransferase_PX28 |
| | Result: | [47] |
| | Not Done: | |
| | LNMT | Low [14] High [36] Unit U/L |
| 5.d | Sponsor ID: | [35] |
| | Test: | Alkaline Phosphatase_PX35 |
| | Result: | [66] |
| | Not Done: | |
| | LNMT | Low [38] High [145] Unit U/L |
| 5.e | Sponsor ID: | [21] |
| | Test: | Bilirubin_PX21 |
| | Result: | [0.5] |
| | Not Done: | |
| | LNMT | Low [0.2] High [1.3] Unit mg/dL |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/01/2021

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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| | | |
|-----|-------------|---|
| 5.f | Sponsor ID: | [47] |
| | Test: | Blood Urea Nitrogen_PX47 |
| | Result: | [28] |
| | Not Done: | |
| | LNMT | Low [7] High [18] Unit mg/dL |

| | | |
|-----|-------------|--|
| 5.g | Sponsor ID: | [48] |
| | Test: | Creatinine_PX48 |
| | Result: | [0.86] |
| | Not Done: | |
| | LNMT | Low [0.50] High [1.40] Unit mg/dL |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Feb/01/2021

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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Lab Chemistry Details

| | | |
|----|-----------------------------|---|
| 1. | Lab Panel: | CLINICAL CHEMISTRY |
| 2. | Laboratory Name and Address | [St. Tammany Parish Hospital 1202 S Tyler St Covington, LA 70433] |
| 3. | Collection Date: | Feb/5/2021 |
| 4. | Specimen Type: | BLOOD |

Lab Result

| | | |
|-----|-------------|---|
| 5.a | Sponsor ID: | [329] |
| | Test: | C Reactive Protein_PX329 |
| | Result: | [] |
| | Not Done: | NOT DONE |
| | LNMT | Low [] High [] Unit |
| 5.b | Sponsor ID: | [30] |
| | Test: | Alanine Aminotransferase_PX30 |
| | Result: | [37] |
| | Not Done: | |
| | LNMT | Low [0] High [35] Unit U/L |

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|--|
| 5.c | Sponsor ID: | [28] |
| | Test: | Aspartate Aminotransferase_PX28 |
| | Result: | [49] |
| | Not Done: | |
| | LNMT | Low [14] High [36] Unit U/L |
| 5.d | Sponsor ID: | [35] |
| | Test: | Alkaline Phosphatase_PX35 |
| | Result: | [60] |
| | Not Done: | |
| | LNMT | Low [38] High [145] Unit U/L |
| 5.e | Sponsor ID: | [21] |
| | Test: | Bilirubin_PX21 |
| | Result: | [0.5] |
| | Not Done: | |
| | LNMT | Low [0.2] High [1.3] Unit mg/dL |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

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| | | |
|-----|-------------|---|
| 5.f | Sponsor ID: | [47] |
| | Test: | Blood Urea Nitrogen_PX47 |
| | Result: | [29] |
| | Not Done: | |
| | LNMT | Low [7] High [18] Unit mg/dL |

| | | |
|-----|-------------|--|
| 5.g | Sponsor ID: | [48] |
| | Test: | Creatinine_PX48 |
| | Result: | [0.94] |
| | Not Done: | |
| | LNMT | Low [0.50] High [1.40] Unit mg/dL |

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Category for Lab Test | Vendor Name (DERIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|--|------------------|---------------|-----------------------------------|-------------------|----------------|---------------------------------|
| 1. | HEMATOLOGY | St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Feb/2/2021 | BLOOD | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | 1 | Hemoglobin_PX1 | 13.9 | |
| | | | | | 2 | Hematocrit_PX2 | 40.6 | |
| | | | | | 3 | Erythrocytes_PX3 | 4.42 | |
| | | | | | 5 | Platelets_PX5 | 105 | |
| | | | | | 7 | Leukocytes_PX7 | 4.87 | |
| | | | | | 608 | Neutrophils_PX608 | 3.5 | |
| | | | | | 609 | Eosinophils_PX609 | 0.0 | |
| | | | | | 612 | Monocytes_PX612 | 0.5 | |
| | | | | | 610 | Basophils_PX610 | 0.02 | |
| | | | | | 611 | Lymphocytes_PX611 | 0.9 | |

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Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 14-Jan-2021 02:24

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Category for Lab Test | Vendor Name (DERIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|--|------------------|---------------|-----------------------------------|-------------------|----------------|---------------------------------|
| 2. | HEMATOLOGY | St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Feb/3/2021 | BLOOD | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | 1 | Hemoglobin_PX1 | 13.9 | |
| | | | | | 2 | Hematocrit_PX2 | 41.0 | |
| | | | | | 3 | Erythrocytes_PX3 | 4.44 | |
| | | | | | 5 | Platelets_PX5 | 129 | |
| | | | | | 7 | Leukocytes_PX7 | 6.28 | |
| | | | | | 608 | Neutrophils_PX608 | 4.4 | |
| | | | | | 609 | Eosinophils_PX609 | 0.0 | |
| | | | | | 612 | Monocytes_PX612 | 0.5 | |
| | | | | | 610 | Basophils_PX610 | 0.01 | |
| | | | | | 611 | Lymphocytes_PX611 | 1.3 | |
| 3. | HEMATOLOGY | St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Feb/4/2021 | BLOOD | Sponsor-Defined Identifier | Test: | Result: | Repeating Pages |
| | | | | | 1 | Hemoglobin_PX1 | 13.2 | |
| | | | | | 2 | Hematocrit_PX2 | 38.2 | |
| | | | | | 3 | Erythrocytes_PX3 | 4.15 | |
| | | | | | 5 | Platelets_PX5 | 135 | |
| | | | | | 7 | Leukocytes_PX7 | 5.24 | |

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Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

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Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

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Generated Time (GMT): 29-Mar-2021 11:56

| # | Category for Lab Test | Vendor Name (DERIVED) | Collection Date: | Specimen Type | Lab Result | | | Form Instance |
|----|-----------------------|---|------------------|---------------|----------------------------|-------------------|---------|---------------------------------|
| | | | | | Sponsor-Defined Identifier | Test: | Result: | |
| | | | | | 608 | Neutrophils_PX608 | 3.3 | |
| | | | | | 609 | Eosinophils_PX609 | 0.0 | |
| | | | | | 612 | Monocytes_PX612 | 0.6 | |
| | | | | | 610 | Basophils_PX610 | 0.00 | |
| | | | | | 611 | Lymphocytes_PX611 | 1.2 | |
| | | | | | | | | |
| 4. | HEMATOLOGY | St. Tammany Parish Hospital 1202 S Tyler St Covington, LA 70121 | Feb/5/2021 | BLOOD | 1 | Hemoglobin_PX1 | 12.7 | Repeating Pages |
| | | | | | 2 | Hematocrit_PX2 | 37.5 | |
| | | | | | 3 | Erythrocytes_PX3 | 4.03 | |
| | | | | | 5 | Platelets_PX5 | 118 | |
| | | | | | 7 | Leukocytes_PX7 | 5.11 | |
| | | | | | 608 | Neutrophils_PX608 | 3.2 | |
| | | | | | 609 | Eosinophils_PX609 | [] | |
| | | | | | 612 | Monocytes_PX612 | [] | |
| | | | | | 610 | Basophils_PX610 | [] | |
| | | | | | 611 | Lymphocytes_PX611 | [] | |

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Form Status: Data Complete

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Laboratory Data Hematology

| | | |
|----|-----------------------------|--|
| 1. | Lab Panel: | HEMATOLOGY |
| 2. | Laboratory Name and Address | [St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433] |
| 3. | Collection Date: | Feb/2/2021 |
| 4. | Specimen Type: | BLOOD |

Lab Result

| | | |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1] |
| | Test: | Hemoglobin_PX1 |
| | Result: | [13.9] |
| | Not Done: | |
| | LNMT | Low [12.0] High [16.0] Unit g/dL |
| 5.b | Sponsor ID: | [2] |
| | Test: | Hematocrit_PX2 |
| | Result: | [40.6] |
| | Not Done: | |
| | LNMT | Low [37.0] High [48.5] Unit % |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/01/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

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| | | |
|-----|-------------|---|
| 5.c | Sponsor ID: | [3] |
| | Test: | Erythrocytes_PX3 |
| | Result: | [4.42] |
| | Not Done: | |
| | LNMT | Low [4.00] High [5.40] Unit /uL |
| 5.d | Sponsor ID: | [5] |
| | Test: | Platelets_PX5 |
| | Result: | [105] |
| | Not Done: | |
| | LNMT | Low [150] High [350] Unit /uL |
| 5.e | Sponsor ID: | [7] |
| | Test: | Leukocytes_PX7 |
| | Result: | [4.87] |
| | Not Done: | |
| | LNMT | Low [3.90] High [12.70] Unit /uL |

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Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

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| | | |
|-----|-------------|--|
| 5.f | Sponsor ID: | [608] |
| | Test: | Neutrophils_PX608 |
| | Result: | [3.5] |
| | Not Done: | |
| | LNMT | Low [1.8] High [7.7] Unit /uL |
| 5.g | Sponsor ID: | [609] |
| | Test: | Eosinophils_PX609 |
| | Result: | [0.0] |
| | Not Done: | |
| | LNMT | Low [0.0] High [0.5] Unit /uL |
| 5.h | Sponsor ID: | [612] |
| | Test: | Monocytes_PX612 |
| | Result: | [0.5] |
| | Not Done: | |
| | LNMT | Low [0.3] High [1.0] Unit /uL |

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Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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| | | |
|-----|-------------|--|
| 5.i | Sponsor ID: | [610] |
| | Test: | Basophils_PX610 |
| | Result: | [0.02] |
| | Not Done: | |
| | LNMT | Low [0.0] High [2.0] Unit /uL |

| | | |
|-----|-------------|--|
| 5.j | Sponsor ID: | [611] |
| | Test: | Lymphocytes_PX611 |
| | Result: | [0.9] |
| | Not Done: | |
| | LNMT | Low [1.0] High [4.8] Unit /uL |

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Subject No: 11471230

Subject Initials: ---

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Laboratory Data Hematology

| | | |
|----|-----------------------------|--|
| 1. | Lab Panel: | HEMATOLOGY |
| 2. | Laboratory Name and Address | [St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433] |
| 3. | Collection Date: | Feb/3/2021 |
| 4. | Specimen Type: | BLOOD |

Lab Result

| | | |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1] |
| | Test: | Hemoglobin_PX1 |
| | Result: | [13.9] |
| | Not Done: | |
| | LNMT | Low [12.0] High [16.0] Unit g/dL |
| 5.b | Sponsor ID: | [2] |
| | Test: | Hematocrit_PX2 |
| | Result: | [41.0] |
| | Not Done: | |
| | LNMT | Low [37.0] High [48.5] Unit % |

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| | | |
|-----|-------------|--|
| 5.c | Sponsor ID: | [3] |
| | Test: | Erythrocytes_PX3 |
| | Result: | [4.44] |
| | Not Done: | |
| | LNMT | Low [4.00] High [5.40] Unit /uL |

| | | |
|-----|-------------|--|
| 5.d | Sponsor ID: | [5] |
| | Test: | Platelets_PX5 |
| | Result: | [129] |
| | Not Done: | |
| | LNMT | Low [150] High [350] Unit /uL |

| | | |
|-----|-------------|---|
| 5.e | Sponsor ID: | [7] |
| | Test: | Leukocytes_PX7 |
| | Result: | [6.28] |
| | Not Done: | |
| | LNMT | Low [3.90] High [12.70] Unit /uL |

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| | | |
|-----|-------------|--|
| 5.f | Sponsor ID: | [608] |
| | Test: | Neutrophils_PX608 |
| | Result: | [4.4] |
| | Not Done: | |
| | LNMT | Low [1.8] High [7.7] Unit /uL |
| 5.g | Sponsor ID: | [609] |
| | Test: | Eosinophils_PX609 |
| | Result: | [0.0] |
| | Not Done: | |
| | LNMT | Low [0.0] High [0.5] Unit /uL |
| 5.h | Sponsor ID: | [612] |
| | Test: | Monocytes_PX612 |
| | Result: | [0.5] |
| | Not Done: | |
| | LNMT | Low [0.3] High [1.0] Unit /uL |

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| | | |
|-----|-------------|---|
| 5.i | Sponsor ID: | [610] |
| | Test: | Basophils_PX610 |
| | Result: | [0.01] |
| | Not Done: | |
| | LNMT | Low [0.0] High [0.20] Unit /uL |

| | | |
|-----|-------------|--|
| 5.j | Sponsor ID: | [611] |
| | Test: | Lymphocytes_PX611 |
| | Result: | [1.3] |
| | Not Done: | |
| | LNMT | Low [1.0] High [4.8] Unit /uL |

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Laboratory Data Hematology

| | | |
|----|-----------------------------|--|
| 1. | Lab Panel: | HEMATOLOGY |
| 2. | Laboratory Name and Address | [St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433] |
| 3. | Collection Date: | Feb/4/2021 |
| 4. | Specimen Type: | BLOOD |

Lab Result

| | | |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1] |
| | Test: | Hemoglobin_PX1 |
| | Result: | [13.2] |
| | Not Done: | |
| | LNMT | Low [12.0] High [16.0] Unit g/dL |
| 5.b | Sponsor ID: | [2] |
| | Test: | Hematocrit_PX2 |
| | Result: | [38.2] |
| | Not Done: | |
| | LNMT | Low [37.0] High [48.5] Unit g/dL |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/01/2021

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| | | |
|-----|-------------|---|
| 5.c | Sponsor ID: | [3] |
| | Test: | Erythrocytes_PX3 |
| | Result: | [4.15] |
| | Not Done: | |
| | LNMT | Low [4.00] High [5.40] Unit /uL |
| 5.d | Sponsor ID: | [5] |
| | Test: | Platelets_PX5 |
| | Result: | [135] |
| | Not Done: | |
| | LNMT | Low [150] High [350] Unit /uL |
| 5.e | Sponsor ID: | [7] |
| | Test: | Leukocytes_PX7 |
| | Result: | [5.24] |
| | Not Done: | |
| | LNMT | Low [3.90] High [12.70] Unit /uL |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/01/2021

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| | | |
|-----|-------------|--|
| 5.f | Sponsor ID: | [608] |
| | Test: | Neutrophils_PX608 |
| | Result: | [3.3] |
| | Not Done: | |
| | LNMT | Low [1.8] High [7.7] Unit /uL |
| 5.g | Sponsor ID: | [609] |
| | Test: | Eosinophils_PX609 |
| | Result: | [0.0] |
| | Not Done: | |
| | LNMT | Low [0.0] High [0.5] Unit /uL |
| 5.h | Sponsor ID: | [612] |
| | Test: | Monocytes_PX612 |
| | Result: | [0.6] |
| | Not Done: | |
| | LNMT | Low [0.3] High [1.0] Unit /uL |

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|--|
| 5.i | Sponsor ID: | [610] |
| | Test: | Basophils_PX610 |
| | Result: | [0.00] |
| | Not Done: | |
| | LNMT | Low [0.00] High [0.20] Unit /uL |

| | | |
|-----|-------------|--|
| 5.j | Sponsor ID: | [611] |
| | Test: | Lymphocytes_PX611 |
| | Result: | [1.2] |
| | Not Done: | |
| | LNMT | Low [1.0] High [4.8] Unit /uL |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/01/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Laboratory Data Hematology

| | | |
|----|-----------------------------|---|
| 1. | Lab Panel: | HEMATOLOGY |
| 2. | Laboratory Name and Address | [St. Tammany Parish Hospital 1202 S Tyler St Covington, LA 70121] |
| 3. | Collection Date: | Feb/5/2021 |
| 4. | Specimen Type: | BLOOD |

Lab Result

| | | |
|-----|-------------|---|
| 5.a | Sponsor ID: | [1] |
| | Test: | Hemoglobin_PX1 |
| | Result: | [12.7] |
| | Not Done: | |
| | LNMT | Low [12.0] High [16.0] Unit g/dL |
| 5.b | Sponsor ID: | [2] |
| | Test: | Hematocrit_PX2 |
| | Result: | [37.5] |
| | Not Done: | |
| | LNMT | Low [37.0] High [48.5] Unit % |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/01/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|---|
| 5.c | Sponsor ID: | [3] |
| | Test: | Erythrocytes_PX3 |
| | Result: | [4.03] |
| | Not Done: | |
| | LNMT | Low [4.00] High [5.40] Unit /uL |
| 5.d | Sponsor ID: | [5] |
| | Test: | Platelets_PX5 |
| | Result: | [118] |
| | Not Done: | |
| | LNMT | Low [150] High [350] Unit /uL |
| 5.e | Sponsor ID: | [7] |
| | Test: | Leukocytes_PX7 |
| | Result: | [5.11] |
| | Not Done: | |
| | LNMT | Low [3.90] High [12.70] Unit /uL |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/01/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|--|
| 5.f | Sponsor ID: | [608] |
| | Test: | Neutrophils_PX608 |
| | Result: | [3.2] |
| | Not Done: | |
| | LNMT | Low [1.8] High [7.7] Unit /uL |
| 5.g | Sponsor ID: | [609] |
| | Test: | Eosinophils_PX609 |
| | Result: | [] |
| | Not Done: | NOT DONE |
| | LNMT | Low [] High [] Unit |
| 5.h | Sponsor ID: | [612] |
| | Test: | Monocytes_PX612 |
| | Result: | [] |
| | Not Done: | NOT DONE |
| | LNMT | Low [] High [] Unit |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Feb/01/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|-------------|-----------------------------------|
| 5.i | Sponsor ID: | [610] |
| | Test: | Basophils_PX610 |
| | Result: | [] |
| | Not Done: | NOT DONE |
| | LNMT | Low [] High [] Unit |
| 5.j | Sponsor ID: | [611] |
| | Test: | Lymphocytes_PX611 |
| | Result: | [] |
| | Not Done: | NOT DONE |
| | LNMT | Low [] High [] Unit |

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Date: | Vital Signs Details | | | Form Instance |
|----|------------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Feb/2/2021 | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |
| | | 1 | 107 | 72 | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 14-Jan-2021 02:17

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Date: | Vital Signs Details | | | Form Instance |
|----|------------|---------------------------|------------------|-------------------|---------------------------------|
| 2. | Feb/3/2021 | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |
| | | 1 | 108 | 65 | |
| 3. | Feb/4/2021 | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |
| | | 1 | 116 | 58 | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Feb/01/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Feb/2/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|--|-------|
| 2.a | Record Identifier: | 1 |
| | Systolic: | [107] |
| | Diastolic: | [72] |
| | Respiratory Rate in respirations/minute: | [20] |
| | Heart Rate in beats/minute: | [114] |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Feb/3/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|--|-------|
| 2.a | Record Identifier: | 1 |
| | Systolic: | [108] |
| | Diastolic: | [65] |
| | Respiratory Rate in respirations/minute: | [17] |
| | Heart Rate in beats/minute: | [68] |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Feb/4/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|--|-------|
| 2.a | Record Identifier: | 1 |
| | Systolic: | [116] |
| | Diastolic: | [58] |
| | Respiratory Rate in respirations/minute: | [16] |
| | Heart Rate in beats/minute: | [78] |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 21-Aug-2020 02:51

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Date: | Vital Signs Details | | Form Instance |
|----|------------|---------------------------|--------------------------|---------------------------------|
| 1. | Feb/2/2021 | Record Identifier: | Oxygen Saturation | Repeating Pages |
| | | 1 | 91.0 | |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 14-Jan-2021 02:17

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Date: | Vital Signs Details | | Form Instance |
|----|------------|---------------------------|--------------------------|---------------------------------|
| 2. | Feb/3/2021 | Record Identifier: | Oxygen Saturation | Repeating Pages |
| | | 1 | 98.0 | |
| 3. | Feb/4/2021 | Record Identifier: | Oxygen Saturation | Repeating Pages |
| | | 1 | 95.0 | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Feb/01/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Feb/2/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|--------|
| 2.a | Record Identifier: | 1 |
| | SPO2 Pulse Oximetry % | [91.0] |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Feb/3/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|--------|
| 2.a | Record Identifier: | 1 |
| | SPO2 Pulse Oximetry % | [98.0] |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

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Vital Signs

| | | |
|----|-------|------------|
| 1. | Date: | Feb/4/2021 |
|----|-------|------------|

Vital Signs Details

| | | |
|-----|-----------------------|--------|
| 2.a | Record Identifier: | 1 |
| | SPO2 Pulse Oximetry % | [95.0] |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Feb/01/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Oxygenation Parameters

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
on Feb/01/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Concomitant Medications

| | | | |
|----|---|--------------------------|--------------------------|
| 1. | What is the medication identifier? | Not Done _____ [] | Comments |
| 2. | Category: | Not Done _____ | Comments |
| 3. | Concomitant Medications Pre-specified: | Not Done _____ | Comments |
| 4. | Medication: Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation). | Not Done _____ [] | Comments |
| 5. | Start Date: | Not Done _____ // | Comments |
| 6. | Ongoing? | Not Done _____ | Comments |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| # | Date of Assessment | Location of Assessment | Imaging Method | Overall Assessment | Form Instance |
|----|--------------------|------------------------|----------------|--|---------------------------------|
| 1. | Feb/2/2021 | CHEST | X-RAY | ABNORMAL <i>If abnormal, specify findings:</i> Patchy infiltrates bilateral bases of lung , no CM | Repeating Pages |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Feb/01/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Imaging

| | | |
|----|-------------------------|---|
| 1. | Date of Assessment: | Feb/2/2021 |
| 2. | Location of Assessment: | CHEST |
| 3. | Type of Imaging Exam: | X-RAY |
| 4. | Assessment: | ABNORMAL If abnormal, specify findings: [Patchy infiltrates bilateral bases of lung, no CM] |

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Mar/03/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Mar/3/2021 |
| 2. | Erroneous Visit | |

COVID-19 Illness Visit

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

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Mar/03/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Mar/3/2021 |
| 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 | [BRZXNM] |
| 5.b | Sample ID | [BRZXP1] |
| 5.c | Sample ID | [BR7X7W] |
| 5.d | Sample ID | [BR7X7X] |

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Unplanned Assessments

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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Disposition - Treatment

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death : | Oct/30/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Disposition - Follow-Up

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Adverse Event Report

| | | |
|-----|---|-----|
| 1. | Category: | |
| 2. | AE ID: | [] |
| 3. | Adverse Event: (If possible specify diagnosis, not individual symptoms) | [] |
| 4. | Start Date Time: | // |
| 5. | Is the adverse event still ongoing? | |
| 6. | Toxicity Grade: | |
| 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). | |
| 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. | |
| 9. | Is this event related to study treatment: | |
| 10. | Latest Action Taken with Study Treatment: | |
| 11. | Was a Concomitant Medication given? | |
| 12. | Was a Non-Drug Treatment given? | |
| 13. | What was the outcome of this adverse event?: | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| | | |
|-----|--|-----|
| 14. | Did the adverse event cause the subject to be discontinued from the study? | |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

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 | [] |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Concomitant Medications

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Concomitant Medications

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: LAB URINALYSIS - PREGNANCY TEST

Form Version: 20-Feb-2021 02:14

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Lab Urinalysis

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

Lab Result

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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? | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Contact Outcome

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Dec/22/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

| | | |
|----|---|--|
| 1. | Select appropriate response - Is participant willing to return for Vaccination 3? | Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 |
|----|---|--|

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Feb/15/2021 |
| 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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|------------|
| 1. | Date of Visit | Mar/3/2021 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

| | | |
|----|--------------|---|
| 1. | Consent Was: | OBTAINED Date Written Consent Obtained Mar/3/2021 |
|----|--------------|---|

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Lab Urinalysis

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

Lab Result

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION

Form Status: Incomplete, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Vaccination

| | | |
|-----|---|---|
| 1. | Was there a temporary delay of vaccination? | YES Date of First Delay: Feb/3/2021 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC CORTICOSTEROID TREATMENT |
| 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? | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 20-Feb-2021 02:14

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Lab Urinalysis

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

Lab Result

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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? | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Queries, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Oct/30/2020 |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Audit Trail](#)

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

- CRF_Sign
- CRF_Sign_1

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|--------------------------|---|
| Form | Sep-09-2020 16:25:16 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | all inclusion criteria met, no exclusion criteria met <hr/> Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| Form | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| 1 | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| 2 | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| 3 | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| 4 | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| 5 | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| 6.a | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| 6.a | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------|--|
| 6.a | Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | Neha Upadhyay (b) (4) | patient not of chilbearing potential Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------------|--|
| 3 | Oct-02-2020 13:35:29 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | menopause 2001 <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------------|--|
| 6.a | Oct-02-2020 13:34:17 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | menopause 2001 <hr/> Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|--------------------------------|----------------|
| 6.a | Oct-02-2020 13:34:17 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | menopause 2001 |
| | | | Not Applicable |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 21-Aug-2020 02:49

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: LAB URINALYSIS - PREGNANCY TEST - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 6.a | Oct-02-2020 13:34:17 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | menopause 2001 |
| | | | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments on Feb/01/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------|
| Form | Feb-04-2021 16:58:17 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/01/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|--|---------------------------|----------|
| 1 | Feb-04-2021 16:58:17 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/01/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|--|---------------------------|----------|
| 2 | Feb-04-2021 16:58:17 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Feb/01/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|--|---------------------------|----------|
| 3 | Feb-04-2021 16:58:17 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------|
| Form | Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------|
| 1 | Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------|
| 2 | Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------|
| 3 | Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------|
| 4 | Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------|
| 5 | Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------|
| 6 | Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Done |

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Item | Date | User | Comment |
|------|---|---------------------------|----------------|
| Form | Mar-03-2021 16:17:07 (UTC-06:00) Central Time (US & Canada) | James McMullen (b) (4) | Not Applicable |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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

- CRF_Sign
- CRF_Sign_1

| Name | Signature Meaning | Date | Type | Action |
|----------------|-------------------|---|------|-----------------------------------|
| James McMullen | N/A | Feb-01-2021 12:02:47 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |

Affidavit:

N/A

| | | | | |
|-------------------|----------|---|------|--------|
| Julia Garcia-Diaz | Approved | Nov-09-2020 15:02:31 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|-------------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, JuliaGarcia-Diaz, 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.

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|-----------------------------------|---------------|
| Sep-09-2020 16:23:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: 24 JUL 2020 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------------------|---------------|
| Sep-09-2020 16:23:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: STAGE 3 COHORTS | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---|---------------|
| Sep-09-2020 16:23:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: OBTAINED Date Written Consent Obtained Sep/9/2020 | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Sep-09-2020 16:23:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11471230 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Sep-09-2020 16:23:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1961 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------|---------------|
| Sep-09-2020 16:24:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: FEMALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--|---------------|
| Sep-09-2020 16:24:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|-----------------------------|---------------|
| Sep-09-2020 16:24:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: WHITE | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------------|---------------|
| Sep-09-2020 16:24:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> Sep/9/2020 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------------|---------------|
| Sep-09-2020 16:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Sep/9/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-09-2020 16:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENING | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------------|---------------|
| Sep-09-2020 16:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:26:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 1 Medical History Term: intractable migraine without aura Start Date: UNK/UNK/2015 Ongoing: YES | Initial Entry |

1.a Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-09-2020 16:26:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------------|-------------------|---|
| Sep-10-2020 18:41:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Patricia Banchemo (b) (4) | Query 1: Closed | Response satisfies query |
| Sep-10-2020 16:33:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | no significant change in therapy or hospitalization for worsening disease occurred during 6wks prior to enrollment. |
| Sep-10-2020 15:33:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Patricia Banchemo (b) (4) | Query 1: Opened | GPDClin: Please confirm if any significant change in therapy or hospitalization for worsening disease occurred for intractable migraine |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|-----------------------|---|--|
| | | | | during the 6weeks prior to enrollment. |
| Sep-09-2020 16:26:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: intractable migraine without aura | Initial Entry |

1.a Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|------------------------------------|---------------|
| Sep-09-2020 16:26:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2015 | Initial Entry |

1.a Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---------------------------|---------------|
| Sep-09-2020 16:26:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|---|---------------|
| Sep-09-2020 16:27:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 2 : Medical History Term: hypertension Start Date: UNK/UNK/2018 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

1.b Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-09-2020 16:27:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:27:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: hypertension | Initial Entry |

1.b Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:27:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2018 | Initial Entry |

1.b Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:27:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-09-2020 16:27:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 3 : Medical History T GERD erm: Start Date: UNK/UNK/2 017 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.c Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-09-2020 16:27:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 3 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------|---------------|
| Sep-09-2020 16:27:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> GERD | Initial Entry |

I.c Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:27:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> UNK/UNK/2017 | Initial Entry |

I.c Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:27:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> YES | Initial Entry |

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-09-2020 16:29:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Num 4 ber: Medical Histo Mild coronary art ry Term: ery disease Start Date: UNK/UNK/2019 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.d Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-09-2020 16:29:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 4 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--|---------------|
| Sep-09-2020 16:29:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Mild coronary artery disease | Initial Entry |

I.d Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:29:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2019 | Initial Entry |

I.d Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:29:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

I.e

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:29:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 5 : Medical History Term: chronic rhinitis Start Date: UNK/UNK/2011 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.e Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-09-2020 16:29:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--|---------------|
| Sep-09-2020 16:29:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> chronic rhinitis | Initial Entry |

I.e Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:29:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> UNK/UNK/2011 | Initial Entry |

I.e Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:29:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> YES | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-09-2020 16:30:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Numb 6 er: Medical History factor V leiden Term: disorder Start Date: UNK/UNK/201 4 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

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If Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-09-2020 16:30:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 6 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--|---|
| Sep-17-2020 19:00:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Sep-16-2020 13:06:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | not exclusionary per pi |
| Sep-13-2020 20:11:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | ClinQuery: There is a Med Hx entry of Factor V Leiden disorder, please confirm if pt meets exclusions criteria #10. |
| Sep-09-2020 16:30:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: factor V leiden disorder | Initial Entry |

If Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:30:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2014 | Initial Entry |

If Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:30:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:30:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 7 : Medical History Term: Insomnia Start Date: UNK/UNK/2019 Ongoing: YES | Initial Entry |

I.g Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|---------------|
| Sep-09-2020 16:30:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--------------------------------|---------------|
| Sep-09-2020 16:30:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Insomnia | Initial Entry |

I.g Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:30:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2019 | Initial Entry |

I.g Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:30:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

I.h

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:31:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 8 Medical History Term: Degenerative disc disease,lumbar Start Date: UNK/UNK/2000 Ongoing: YES | Initial Entry |

1.h Line/MH Number:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Sep-09-2020 16:31:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 8 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--|---------------|
| Sep-09-2020 16:31:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Degenerative disc disease,lumbar | Initial Entry |

1.h Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:31:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2000 | Initial Entry |

1.h Ongoing:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:31:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

1.i

| Date | Location | User | Value | Reason |
|----------------------|-----------------|-----------|--------------------|---------------|
| Sep-09-2020 16:32:35 | ACV0PFEINFP6000 | auto calc | Data Entry: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| | | | |
|--|--|------------|---|
| (UTC-06:00) Central Time (US & Canada) | | (autocalc) | Line/MH Number: 9 Medical History Term: cervical radiculopathy Start Date: UNK/UNK/2000 Ongoing: YES |
|--|--|------------|---|

1.i Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|----------------------|---------------|
| Sep-09-2020 16:32:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 9 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---|---------------|
| Sep-09-2020 16:32:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: cervical radiculopathy | Initial Entry |

1.i Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------|---------------------------------|---------------|
| Sep-09-2020 16:32:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2000 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1.i Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:32:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

1.j

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:33:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 10 : Medical History Term: right foot pain Start Date: UNK/UNK/2017 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

1.j Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-09-2020 16:33:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 10 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------------------|---------------|
| Sep-09-2020 16:33:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: right foot pain | Initial Entry |

1.j Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:33:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2017 | Initial Entry |

1.j Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:33:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

1.k

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:33:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 11 Medical History: allergic to hydro Term: codone Start Date: UNK/UNK/200 0 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.k Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-09-2020 16:33:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 11 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---|---------------|
| Sep-09-2020 16:33:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> allergic to hydrocodone | Initial Entry |

I.k Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:33:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> UNK/UNK/2000 | Initial Entry |

I.k Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:33:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | <u>Data Entry:</u> YES | Initial Entry |

I.l

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:34:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Line/MH Number: 12 Medical History Term: allergic to oxycodone Start Date: UNK/UNK/2000 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

1.1 Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-09-2020 16:34:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 12 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---|---------------|
| Sep-09-2020 16:34:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: allergic to oxycodone | Initial Entry |

1.1 Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:34:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2000 | Initial Entry |

1.1 Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:34:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

1.m

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:35:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number: 13 Medical History: allergic doxycycline Term: ycline Start Date: UNK/UNK/2018 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.m Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-09-2020 16:35:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 13 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--|---------------|
| Sep-09-2020 16:35:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: allergic doxycycline | Initial Entry |

I.m Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:35:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2018 | Initial Entry |

I.m Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:35:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

I.n

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Sep-09-2020 16:36:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Line/MH Number 14 : Medical History T menopausal erm: Start Date: UNK/UNK/2 001 Ongoing: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

I.n Line/MH Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Sep-09-2020 16:36:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 14 | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------------|---------------|
| Sep-09-2020 16:36:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: menopausal | Initial Entry |

I.n Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------------|---------------|
| Sep-09-2020 16:36:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: UNK/UNK/2001 | Initial Entry |

I.n Ongoing:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:36:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|----------------------------------|---|
| Sep-09-2020 16:39:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Closed | Close Auto Query |
| Sep-09-2020 16:39:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-09-2020 16:39:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Sep/9/2020 | Transcription Error |
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Opened | Collection Date, 09/Sep/2022 is a future date relative to when it was entered on 09/Sep /2020. Please correct. |
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Vital signs Date 09/Sep/2022 is not same as Date of Visit 09/Sep/2020. Please review and update as appropriate or clarify. |
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Sep/9/2022 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|-----------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: 226.0 | Initial Entry |

3. Unit:

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: LB | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: 64.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: in | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 38.8 | Initial Entry |

7.a

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Record Identifier 1 :: Temperature: 97.9 Temperature Unit: Temperature Location: ORAL CAVITY | Initial Entry |

7.a Record Identifier:

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|--------------------------|-------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: 1 | Initial Entry |
|---|-----------------|--------------------------|-------------------------|---------------|

7.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: 97.9 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|-------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|-----------------------------------|---------------|
| Sep-09-2020 16:37:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

2. Lab Sub-Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

4. Laboratory Name and Address (Derived)

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

5. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

6.a

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|-----------------|--------------------------|---|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable | Initial Entry |
|--|-----------------|--------------------------|---|---------------|

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

6.a Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|--------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:38:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------------|---------------|
| Sep-09-2020 16:39:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Sep/9/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|------------------------------|---------------|
| Sep-09-2020 16:39:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: 253202 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Sep-09-2020 16:39:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Sep-09-2020 16:39:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|--|
| Sep-10-2020 09:00:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-10-2020 06:58:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-09-2020 16:39:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-09-2020 16:39:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES Date of Collection: Sep/9/2020 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 09:00:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPLF4V | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 09:00:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPLF4V | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 09:00:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPY3DS | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 09:00:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPY3DS | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 09:00:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPY3DT | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 09:00:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPY3DT | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 09:00:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPY3DV | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 09:00:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPY3DV | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 09:01:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPLF4D | Initial Entry |

5.e Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 09:01:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPLF4D | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-09-2020 16:39:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-09-2020 16:39:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Sep-10-2020 08:58:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Sep-10-2020 06:58:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-09-2020 16:39:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Sep-09-2020 16:39:57 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES Date of Collection: Sep/9/2020 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Sep-10-2020 08:58:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BPY3D6 | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-10-2020 08:58:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BPY3D6 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--------------------------|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: Sep/9/2020 13:39 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|----------------------------|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: LEFT | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED O BSERVATION PERIOD | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|---------------------------|---------------|
| Sep-09-2020 16:41:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|--------------------------|--|---------------|
| Sep-09-2020 16:41:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Neha Upadhyay (b) (4) | Data Entry: NO - REACTOGENICITY E-D IARY NOT COLLECTED FO R THIS SUBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Oct-02-2020 13:31:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Oct/2/2020 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Oct-02-2020 13:32:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/2/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-02-2020 13:32:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier 1 : Temperature: 98.6 Temperature Unit F : Temperature Loc ORAL CAV ation: ITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-02-2020 13:32:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Temperature:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------|---------------|
| Oct-02-2020 13:32:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 98.6 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Oct-02-2020 13:32:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------------------------|-----------------------------------|---------------|
| Oct-02-2020 13:32:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] | Data Entry: ORAL CAVITY | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-02-2020 13:35:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-02-2020 13:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined I Not Appli dentifier: cable Test:: Not Appli cable Result:: Not Appli cable Not Done:: Not Appli cable | Initial Entry |

6.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-02-2020 13:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Oct-02-2020 13:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

6.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------|--------------------------------------|---------------|
| Oct-02-2020 13:34:17 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)

(b) (4)

6.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Oct-02-2020 13:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-02-2020 13:34:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Oct-02-2020 13:34:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Oct-02-2020 17:15:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-02-2020 13:34:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-02-2020 13:34:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/2/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Oct-02-2020 17:15:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sample ID: BR7XC3 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|------------------------------|---------------|
| Oct-02-2020 17:15:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: BR7XC3 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Oct-02-2020 13:36:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Oct-02-2020 13:36:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLINDED THERAPY | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Oct-02-2020 13:36:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Oct-02-2020 13:36:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/2/2020 09:44 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Oct-02-2020 13:36:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|---|-----------------|---------|-----------------------------|---------------|
| Oct-02-2020 13:36:08 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (6) | Data Entry: RIGHT | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)

(b) (4)

7. Route:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|---------------|
| Oct-02-2020 13:36:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Oct-02-2020 13:36:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED O BSERVATION 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-02-2020 13:36:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|-----------------------------------|---------------|
| Oct-30-2020 11:19:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Fredrick Okwori (b) (4) | Data Entry: Oct/30/2020 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471230**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-30-2020 11:19:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Oct-30-2020 11:19:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---|---|
| Nov-02-2020 04:31:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-30-2020 11:19:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Oct-30-2020 11:19:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Fredrick Okwori (b) (4) | Data Entry: YES Date of Collection: Oct/30/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-02-2020 04:31:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BMNV16 | Initial Entry |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-02-2020 04:31:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BMNV16 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-02-2020 04:38:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BMNV1G | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-02-2020 04:38:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BMNV1G | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-02-2020 04:41:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BR7XM1 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-02-2020 04:41:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BR7XM1 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Nov-02-2020 04:47:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BR7XM0 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Nov-02-2020 04:47:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BR7XM0 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Feb/01/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------|---|
| Feb-24-2021 04:02:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-23-2021 17:15:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Answer Auto Query |
| Feb-16-2021 02:25:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Per comment 'Site will update self-swab when available'. Please verify if the swabs details are available & update the details in corresponding CRF. Thanks |
| Feb-03-2021 05:25:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Candidate | Please update when data is available. Thank you. |
| Feb-02-2021 16:18:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | Site will update self-swab when available. |
| Feb-02-2021 14:06:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Please complete the data that is known at this time and update once possible. |
| Feb-02-2021 08:57:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | Site has not received self swab from the subject yet |
| Feb-02-2021 02:48:27 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Feb/01/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471230**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

| | | | | |
|--|-----------------|---------------------------|----------------------------------|--|
| | | | | Swab are missing. Please review and update as appropriate. |
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Feb-01-2021 12:02:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Candidate | Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate. |
| Feb-01-2021 12:02:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate. |
| Feb-01-2021 12:02:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/1/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|-------------------------------|---------------|
| Feb-01-2021 12:02:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471230**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)**1. Date of Assessment:**

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/1/2021 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Jan/29/2021 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|-----------------|
| Mar-03-2021 16:22:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | New Information |
| Feb-22-2021 15:17:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NO Date of Last Symptom Resolved: Feb/20/2021 | New Information |
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Symptoms: FEVER Symptom Present: YES | Initial Entry |

4.a Symptoms:

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: FEVER | Initial Entry |

4.a Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

4.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Symptoms NEW OR INCREASED COUGH Symptom YES Present: | Initial Entry |

4.b Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sympto NEW OR INCREASED | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | ms: ED SHORTNESS OF BREATH Symptom Present: YES | |
|--|--|--|--|--|

4.c Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NEW OR INCREASED SHORTNESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Symptoms: CHILLS Symptom Present: YES | Initial Entry |

4.d Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|-----------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Symptom NEW OR INCREASED MUSCLE PAIN Symptom YES Present: | Initial Entry |

4.e Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Symptom NEW LOSS OF TASTE OR SMELL Symptom YES Present: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.f Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

4.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Symptoms: NEW OR INCREASED SORE THROAT Symptom Present: YES | Initial Entry |

4.g Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NEW OR INCREASED SORE THROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

4.h

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|------------------------------|---|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Symptoms: DIARRHEA A Symptom Present: YES | Initial Entry |
|---|-----------------|------------------------------|---|---------------|

4.h Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Symptoms: VOMITIN G Symptom Present: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

4.i Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------|---------------|
| Feb-01-2021 12:03:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Feb/01/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-02-2021 08:36:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/01/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------------------------|---|
| Feb-03-2021 05:30:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-02-2021 16:17:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | Subject planned to send results to site but was admitted to ER. Forms updated. |
| Feb-02-2021 14:05:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Please update the Trade Name of the sample per CCGs section 8.31.4• If the Trade Name is not known, enter "NALT Unknown". |
| Feb-02-2021 08:36:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Jan/30/2021 | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:36:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: SWABBED MATERIAL | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-----------------------------------|---------------|
| Feb-02-2021 08:36:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NASOPHARYNX | Initial Entry |

4. Assay Code and Description:

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Feb/01/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:36:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SEVERE ACUTE RESP SYNDR OME CORONAVIRUS 2 | Initial Entry |
|---|-----------------|-------------------------|--|---------------|

5. Device Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:36:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SARS-COV-2 DIAGNOSTIC TES T | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------|---------------|
| Feb-02-2021 16:17:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: OTHER | Initial Entry |

7. Test Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-02-2021 08:36:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: POSITIVE | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|------------------------------------|---------------|
| Feb-02-2021 16:17:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NALT Unknown | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-23-2021 17:15:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Feb-23-2021 17:15:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---|
| Feb-23-2021 17:16:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-23-2021 17:15:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-23-2021 17:15:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES Date of Collection: Feb/22/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-23-2021 17:16:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sample ID: RW89794 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-------------------------------|---------------|
| Feb-23-2021 17:16:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: RW89794 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit
on Feb/01/2021

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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-01-2021 12:04:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-01-2021 12:04:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-01-2021 12:04:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-01-2021 12:04:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Site did not collect swab | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/01/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Type of Practitioner SPECIA : LIST Occurrence of Visits NO or Contacts: | Initial Entry |

1.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: SPECIALIST | Initial Entry |

1.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NO | Initial Entry |

1.b

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Type of Practi EMERGENC tioner: Y ROOM Occurrence of YES Visits or Cont <i>Number of Vi</i> acts: <i>sits or Conta</i> <i>cts:</i> 1 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/01/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------------|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: EMERGENCY ROOM | Initial Entry |

I.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

I.c

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO | Initial Entry |

I.c Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

I.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NO | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/01/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

I.d

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

I.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: URGENT CARE | Initial Entry |

I.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

I.e

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/01/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471230**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56***1.e Physician or Healthcare Professional:***

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: TELEPHONE CONSULTATIO N | Initial Entry |

1.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NO | Initial Entry |

1.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Type of Practitioner: OTH ER Occurrence of Visits or NO Contacts: | Initial Entry |

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|----------------------|-----------------|---------|-----------------|--------------------|
| Feb-11-2021 15:03:01 | ACV0PFEINFP6000 | (b) (6) | Query 1: Closed | Response satisfies |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Feb/01/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|-----------------|--|--|---|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | | query |
| Feb-09-2021 16:33:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | CRFs updated |
| Feb-09-2021 14:57:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Query 1: Reissued:Opened | Clin: Did subject receive respiratory treatment? If so, please complete RESP TX CRF. |
| Feb-04-2021 17:06:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | Forms entered |
| Feb-03-2021 10:55:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [REDACTED] [REDACTED] | Query 1: Opened | Clin: As subject was hospitalized, please complete RESP TX, OXYGEN, and VASOPRESS CRFs as applicable. |
| Feb-02-2021 08:35:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES Has the subject been in intensive care due to potential COVID-19 illness? NO | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - Audit Trail
on Feb/01/2021

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-02-2021 08:44:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History on Feb/01/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Hospitalization Category:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:44:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: HOSPITALIZATION STATUS | Initial Entry |

2. Hospitalization Term:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------|
| Feb-02-2021 08:44:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: HOSPITAL | Initial Entry |

3. Admission Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-02-2021 08:44:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/2/2021 | Initial Entry |

4. Ongoing?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|-------------------------------|
| Mar-04-2021 08:15:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-04-2021 07:36:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Mar-04-2021 07:36:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NO Discharge Date: Feb/6/2021 | Changed Information |
| Mar-03-2021 16:44:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Clin: Please record end date. |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** HOSPITALIZATION DETAILS - eCRF Audit Trail History on Feb/01/2021

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|------------------------------|---------------------------|---------------|
| Feb-02-2021 08:44:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> YES | Initial Entry |
|---|-----------------|------------------------------|---------------------------|---------------|

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Audit Trail
on Feb/01/2021

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-09-2021 16:32:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/01/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. What is the treatment Identifier?

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-09-2021 16:32:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

2. Concomitant Non-drug Treatment Pre-specified:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-09-2021 16:32:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: YES | Initial Entry |

3. Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-09-2021 16:32:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: HIGH FLOW OXYGEN THER APY | Initial Entry |

4. Treatment:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-09-2021 16:32:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: HIGH FLOW OXYGEN THERAP Y | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-09-2021 16:32:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/2/2021 | Initial Entry |

6. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------|-----------------|--------------------------|
| Mar-04-2021 08:15:45 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (6) | Query 1: Closed | Response satisfies query |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Feb/01/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|--|---|----------------------------------|
| Time (US & Canada) | | (b) (4) | | |
| Mar-04-2021 07:36:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Mar-04-2021 07:36:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NO End Date: Feb/6/2021 | Changed Information |
| Mar-03-2021 16:45:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) [redacted] [redacted] | Query 1: Opened | Clin: Please record end date. |
| Feb-09-2021 16:32:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Feb/01/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-01-2021 12:04:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: POTENTIAL COVID-19 ILLNES S | Initial Entry |

2. Was a diagnosis obtained for Potential COVID-19 Illness?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-01-2021 12:04:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COVID-19 Date of Diagnosis: Jan/30/2021 | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-------------------------|---------------|
| Feb-01-2021 12:04:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 2 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

Form Version: 21-Aug-2020 02:49

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: CLINICAL CHEMISTRY | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|-----------------|
| Feb-04-2021 17:20:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | New Information |
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Ochsner Medical Center 1514 Jefferson Hwy. New Orleans, LA 70121 | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/2/2021 | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLOOD | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Define 329 d Identifier: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Test:: C Reactive Protein_PX329 Result:: 5.50 Not Done: Lab Normal Range: Low 0.00 High 0.90 Unit mg/dL | |
|--|--|--|--|--|

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 329 | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: C Reactive Protein_PX329 | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 5.50 | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-------------------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Low 0.00 High | Initial Entry |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Generated By: (b) (4)

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| | | | | |
|--|--|--|----------------------|--|
| | | | 0.90 | |
| | | | <i>Unit</i> mg/dL | |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: 30 Not Done: Lab Normal Range: <i>Low</i> 0 <i>High</i> 35 <i>Unit</i> U/L | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

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Site Name: (1147) Ochsner Health System

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Generated By: (b) (4)

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5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 30 | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Alanine Aminotransferase_PX3 0 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 30 | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0 <i>High</i> 35 <i>Unit</i> U/L | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Aspartate Aminotransferase_PX28 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

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Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------|--|
| | | | Result:: 44 | |
| | | | Not Done:: | |
| | | | Lab Normal <i>Low</i> | |
| | | | Range: 14 | |
| | | | <i>High</i> | |
| | | | 36 | |
| | | | <i>Unit</i> | |
| | | | U/L | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 28 | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Aspartate Aminotransferase_PX 28 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 44 | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Low 14 High 36 Unit U/L | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Define d Identifier: 35 Test:: Alkaline Phosphatase_PX35 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

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Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Result:: 80 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> 38 | |
| | | | <i>High</i> 145 | |
| | | | <i>Unit</i> U/L | |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

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Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 35 | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 80 | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 38 High 145 Unit U/L | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 21 entifier: Test:: Bilirubin_P X21 | Initial Entry |

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 0.6 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 0.2 | |
| | | | <i>High</i> | |
| | | | 1.3 | |
| | | | <i>Unit</i> | |
| | | | mg/dL | |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Subject Initials: ---

Generated By: (b) (4)

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5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 21 | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.6 | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 0.2 High 1.3 Unit mg/dL | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Define 47 d Identifier: Test:: Blood Urea Nitrogen_PX47 | Initial Entry |

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Header Text: c4591001

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Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 20 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 7 | |
| | | | <i>High</i> | |
| | | | 18 | |
| | | | <i>Unit</i> | |
| | | | mg/dL | |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 47 | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 20 | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 7 High 18 Unit mg/dL | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48 | Initial Entry |

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 1.11 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 0.50 |
| | | | | <i>High</i> |
| | | | | 1.40 |
| | | | | <i>Unit</i> |
| | | | | mg/dL |

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Generated By: (b) (4)

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5.g Sponsor ID:

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| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 48 | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Creatinine_PX48 | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 1.11 | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:44:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 0.50 High 1.40 Unit mg/dL | Initial Entry |

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Header Text: c4591001

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: CLINICAL CHEMISTRY | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:20:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Changed Information |
| Feb-04-2021 17:18:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Ochsner Medical Center 1514 Jefferson Highway New Orleans, LA 70121 | Changed Information |
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Ochsner Medical Center | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/3/2021 | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLOOD | Initial Entry |

5.a

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

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Define 329 d Identifier: Test:: C Reactive Prot ein_PX329 Result:: Not Done:: NOT DONE Lab Normal Ra nge: | Initial Entry |
|---|-----------------|-------------------------|---|---------------|

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 329 | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: C Reactive Protein_PX329 | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NOT DONE | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defin 30 ed Identifier: Test:: Alanine Aminotra nsferase_PX30 Result:: 37 Not Done:: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Lab Normal Range: <i>Low</i> 0 <i>High</i> 35 <i>Unit</i> U/L | |
|--|--|--|--|--|

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Alanine Aminotransferase_PX3 0 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 37 | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 0 <i>High</i> 35 <i>Unit</i> U/L | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Aspartate Aminotransferase_PX28 Result:: 48 Not Done:: Lab Normal Range: Low 14 High 36 Unit U/L | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 28 | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Aspartate Aminotransferase_PX 28 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 48 | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 14 High 36 Unit U/L | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:13:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Sponsor-Defi ned Identifier 35 : | Transcription Error |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|-------------------------|--|---------------|
| | | | Test:: Alkaline Phos phatase_PX35 Result:: 76 Not Done:: Lab Normal Range: <i>Low</i> 38 <i>High</i> 145 <i>Unit</i> U/L | |
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier 35 : Test:: Alkaline Phos phatase_PX35 Result:: 76 Not Done:: Lab Normal Range: <i>Low</i> 38 <i>High</i> 145 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 35 | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|--|
| Feb-04-2021 17:13:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm. |
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 76 | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------------|
| Feb-04-2021 17:13:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 38 High 145 Unit | Transcription Error |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|------------------------------|--|---------------|
| | | | U/L | |
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 38 <i>High</i> 145 | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 21 Test:: Bilirubin_P X21 Result:: 0.6 Not Done:: Lab Normal Range: <i>Low</i> 0.2 <i>High</i> 1.3 <i>Unit</i> mg/dL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 21 | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 0.6 | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 0.2 <i>High</i> 1.3 <i>Unit</i> mg/dL | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------------|
| Feb-04-2021 17:14:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier 47 : | Changed Information |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|----------------------|--|---------------|
| | | | Test:: Blood Urea Nitrogen_PX47 Result:: 25 Not Done:: Lab Normal Range: <i>Low</i> 7 <i>High</i> 18 <i>Unit</i> mg/dL | |
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 47 Test:: Blood Urea Nitrogen_PX47 Result:: Not Done:: NOT DONE Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 47 | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------------|
| Feb-04-2021 17:14:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 25 | Changed Information |

5.f Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------------|
| Feb-04-2021 17:14:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> | Changed Information |
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> NOT DONE | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------------|
| Feb-04-2021 17:14:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 7 High 18 | Changed Information |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|----------------------|--|
| | | | <i>Unit</i> mg/dL | |
|--|--|--|----------------------|--|

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48 Result:: 1.03 Not Done:: Lab Normal Range <i>Low</i> : 0.50 <i>High</i> 1.40 <i>Unit</i> mg/dL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 48 | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Creatinine_PX48 | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 1.03 | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-04-2021 17:12:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0.50 <i>High</i> 1.40 <i>Unit</i> mg/dL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: CLINICAL CHEMISTRY | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:21:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Changed Information |
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Ochsner Medical Center 1514 Jefferson Highway New Orleans, LA 70121 | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/4/2021 | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLOOD | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Define 329 d Identifier: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Test:: C Reactive Protein_PX329 Result:: 2.40 Not Done:: Lab Normal Range: <i>Low</i> 0.00 <i>High</i> 0.90 <i>Unit</i> mg/dL | |
|--|--|--|--|--|

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 329 | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: C Reactive Protein_PX329 | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|-------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 2.40 | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 0.00 <i>High</i> | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|----------------------|--|
| | | | 0.90 | |
| | | | <i>Unit</i> mg/dL | |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: 38 Not Done: Lab Normal Range: <i>Low</i> 0 <i>High</i> 35 <i>Unit</i> U/L | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 30 | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Alanine Aminotransferase_PX3 0 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 38 | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0 <i>High</i> 35 <i>Unit</i> U/L | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Aspartate Aminotransferase_PX28 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------|--|
| | | | Result:: 47 | |
| | | | Not Done:: | |
| | | | Lab Normal <i>Low</i> | |
| | | | Range: 14 | |
| | | | <i>High</i> | |
| | | | 36 | |
| | | | <i>Unit</i> | |
| | | | U/L | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 28 | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Aspartate Aminotransferase_PX 28 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 47 | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 14 High 36 Unit U/L | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Define 35 d Identifier: Test:: Alkaline Phosphatase_PX35 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Result:: 66 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> 38 | |
| | | | <i>High</i> 145 | |
| | | | <i>Unit</i> U/L | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 35 | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 66 | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 38 High 145 Unit U/L | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 21 entifier: Test:: Bilirubin_P X21 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 0.5 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 0.2 | |
| | | | <i>High</i> | |
| | | | 1.3 | |
| | | | <i>Unit</i> | |
| | | | mg/dL | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 21 | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 0.5 | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 0.2 <i>High</i> 1.3 <i>Unit</i> mg/dL | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Define 47 d Identifier: Test:: Blood Urea Nitrogen_PX47 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 28 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 7 | |
| | | | <i>High</i> | |
| | | | 18 | |
| | | | <i>Unit</i> | |
| | | | mg/dL | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 47 | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 28 | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 7 High 18 Unit mg/dL | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 0.86 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 0.50 |
| | | | | <i>High</i> |
| | | | | 1.40 |
| | | | | <i>Unit</i> |
| | | | | mg/dL |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 48 | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Creatinine_PX48 | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.86 | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:17:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0.50 <i>High</i> 1.40 <i>Unit</i> mg/dL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: CLINICAL CHEMISTRY | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: St. Tammany Parish Hospital 1202 S Tyler St Covington, LA 70433 | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/5/2021 | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLOOD | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Define d Identifier: 329 Test:: C Reactive Protein_PX329 Result:: Not Done:: NOT DONE | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------|--|
| | | | Lab Normal Range: | |
|--|--|--|-------------------|--|

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|---------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 329 | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: C Reactive Protein_PX329 | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NOT DONE | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: 37 Not Done:: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Lab Normal Range: <i>Low</i> 0 <i>High</i> 35 <i>Unit</i> U/L | |
|--|--|--|--|--|

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Alanine Aminotransferase_PX3 0 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 37 | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 0 <i>High</i> 35 <i>Unit</i> U/L | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Aspartate Aminotransferase_PX28 Result:: 49 Not Done:: Lab Normal Range: <i>Low</i> 14 <i>High</i> 36 <i>Unit</i> U/L | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 28 | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Aspartate Aminotransferase_PX 28 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 49 | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 14 High 36 Unit U/L | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Define 35 d Identifier: Test:: Alkaline Phosphatase_PX35 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Result:: 60 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> 38 | |
| | | | <i>High</i> 145 | |
| | | | <i>Unit</i> U/L | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 35 | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Alkaline Phosphatase_PX35 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 60 | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 38 High 145 Unit U/L | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 21 entifier: Test:: Bilirubin_P X21 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 0.5 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 0.2 | |
| | | | <i>High</i> | |
| | | | 1.3 | |
| | | | <i>Unit</i> | |
| | | | mg/dL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 21 | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Bilirubin_PX21 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.5 | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 0.2 High 1.3 Unit mg/dL | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Define 47 d Identifier: Test:: Blood Urea Nitrogen_PX47 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 29 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 7 | |
| | | | <i>High</i> | |
| | | | 18 | |
| | | | <i>Unit</i> | |
| | | | mg/dL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 47 | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Blood Urea Nitrogen_PX47 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 29 | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 7 High 18 Unit mg/dL | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 0.94 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 0.50 |
| | | | | <i>High</i> |
| | | | | 1.40 |
| | | | | <i>Unit</i> |
| | | | | mg/dL |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:30

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 48 | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Creatinine_PX48 | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.94 | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:30:50 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0.50 <i>High</i> 1.40 <i>Unit</i> mg/dL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 21-Aug-2020 02:51

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: HEMATOLOGY | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------------|
| Feb-04-2021 17:21:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Ochsner Medical Center 1514 Jefferson Hwy. New Orleans, LA 70121 | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/2/2021 | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLOOD | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined I 1 dentifier: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|---|--|
| | | | Test:: Hemoglobin _PX1 Result:: 13.9 Not Done:: Lab Normal Range <i>Low</i> : 12.0 <i>High</i> 16.0 <i>Unit</i> g/dL | |
|--|--|--|---|--|

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Hemoglobin_PX1 | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 13.9 | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 12.0 <i>High</i> | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|---------------------|--|
| | | | 16.0 | |
| | | | <i>Unit</i> g/dL | |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_PX2 Result:: 40.6 Not Done:: Lab Normal Range <i>Low</i> : 37.0 <i>High</i> 48.5 <i>Unit</i> % | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 2 | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 40.6 | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 37.0 High 48.5 Unit % | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 3 identifier: Test:: Erythrocytes _PX3 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 4.42 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 4.00 |
| | | | | <i>High</i> |
| | | | | 5.40 |
| | | | <i>Unit</i> | |
| | | | /uL | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 3 | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 4.42 | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 4.00 High 5.40 Unit /uL | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Platelets_P X5 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 105 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 150 | |
| | | | <i>High</i> | |
| | | | 350 | |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Platelets_PX5 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 105 | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 150 High 350 Unit /uL | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 7 entifier: Test:: Leukocytes_PX7 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 4.87 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 3.90 |
| | | | | <i>High</i> |
| | | | | 12.70 |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 7 | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 4.87 | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Low 3.90 High 12.70 Unit /uL | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:06:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 | Changed Information |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|---|---------------------|
| | | | Result:: 3.5 Not Done:: Lab Normal Range: <i>Low</i> 1.8 <i>High</i> 7.7 <i>Unit</i> /uL | |
| Feb-04-2021 17:05:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: 3.5 Not Done:: Lab Normal Range: <i>Low</i> 38.0 <i>High</i> 73.0 <i>Unit</i> % | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_PX608 Result:: 71.2 Not Done:: Lab Normal Range: <i>Low</i> 38.0 <i>High</i> 73.0 <i>Unit</i> % | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 608 | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Neutrophils_PX608 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|---|---------------------------|---------------------------|--|
| Feb-04-2021 20:36:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Closed | Auto closed by Validation Check: VC_LB001_08 |
| Feb-04-2021 17:05:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Feb-04-2021 17:05:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 3.5 | Changed Information |
| Feb-03-2021 02:18:41 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW7110592;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

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Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|------------------------|----------------------------|-------------------------|
| | | | | correct as appropriate. |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 71.2 | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------------|
| Feb-04-2021 17:06:05 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 1.8 <i>High</i> 7.7 <i>Unit</i> /uL | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 38.0 <i>High</i> 73.0 <i>Unit</i> % | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------|---|---------------------|
| Feb-04-2021 17:27:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Define 609 d Identifier: Test:: Eosinophils_PX609 Result:: 0.0 Not Done:: | Changed Information |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|----------------------|---|---------------|
| | | | Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 0.5 <i>Unit</i> /uL | |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 609 Test: Eosinophils_PX609 Result: 0 Not Done: Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 9.0 <i>Unit</i> % | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 609 | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Eosinophils_PX609 | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------------|
| Feb-04-2021 17:27:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.0 | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0 | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:27:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0.0 <i>High</i> 0.5 <i>Unit</i> /uL | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0.0 <i>High</i> | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------|--|
| | | | 9.0 | |
| | | | <i>Unit</i> | |
| | | | % | |

5.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------------|
| Feb-04-2021 17:27:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_PX612 Result:: 0.5 Not Done:: Lab Normal Range: <i>Low</i> 0.3 <i>High</i> 1.0 <i>Unit</i> /uL | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_PX612 Result:: 9.7 Not Done:: Lab Normal Range: <i>Low</i> 4.0 <i>High</i> 15.0 <i>Unit</i> % | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 612 | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Monocytes_PX612 | Initial Entry |

5.h Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------|------------------------|
| Feb-04-2021 17:27:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.5 | Changed Information |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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5.h Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 9.7 | Initial Entry |

5.h LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:27:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 0.3 <i>High</i> 1.0 <i>Unit</i> /uL | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 4.0 <i>High</i> 15.0 <i>Unit</i> % | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------------|
| Feb-04-2021 17:28:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_PX610 Result:: 0.02 Not Done:: | Changed Information |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|----------------------|--|---------------|
| | | | Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 2.0 <i>Unit</i> /uL | |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_PX610 Result:: 0.2 Not Done:: Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 1.9 <i>Unit</i> % | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 610 | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Basophils_PX610 | Initial Entry |

5.i Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------------|
| Feb-04-2021 17:28:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.02 | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.2 | Initial Entry |

5.i LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:28:15 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0.0 <i>High</i> 2.0 <i>Unit</i> /uL | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 0.0 <i>High</i> | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------|--|
| | | | 1.9 | |
| | | | <i>Unit</i> | |
| | | | % | |

5.j

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:29:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 0.9 Not Done:: Lab Normal Range: <i>Low</i> 1.0 <i>High</i> 4.8 <i>Unit</i> /uL | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_PX611 Result:: 18.5 Not Done:: Lab Normal Range: <i>Low</i> 18.0 <i>High</i> 48.0 <i>Unit</i> % | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 611 | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Lymphocytes_PX611 | Initial Entry |

5.j Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------------|
| Feb-04-2021 17:29:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.9 | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 18.5 | Initial Entry |

5.j LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------------|
| Feb-04-2021 17:29:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 1.0 <i>High</i> 4.8 <i>Unit</i> /uL | Changed Information |
| Feb-02-2021 08:54:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 18.0 <i>High</i> | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------|--|
| | | | 48.0 | |
| | | | <i>Unit</i> | |
| | | | % | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 14-Jan-2021 02:24

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 14-Jan-2021 02:24

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 14-Jan-2021 02:24

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: HEMATOLOGY | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/3/2021 | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLOOD | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined 1 Identifier: Test:: Hemoglobin_PX1 Result:: 13.9 Not Done:: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|--|---------------|
| | | | Lab Normal Range: <i>Low</i> 12.0 <i>High</i> 16.0 <i>Unit</i> g/dL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: Not Done:: Lab Normal Range: | Initial Entry |

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|----------------------|-------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Hemoglobin_PX1 | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 13.9 | Initial Entry |

5.a LNMT

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 12.0 <i>High</i> 16.0 <i>Unit</i> g/dL | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit _PX2 Result:: 41.0 Not Done:: Lab Normal Range: <i>Low</i> 37.0 <i>High</i> 48.5 <i>Unit</i> % | Initial Entry |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit _PX2 Result:: Not Done:: Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 2 | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 41.0 | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 37.0 <i>High</i> 48.5 <i>Unit</i> % | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|--|---------------|
| | | | Result:: 4.44 Not Done:: Lab Normal Range: <i>Low</i> 4.00 <i>High</i> 5.40 <i>Unit</i> /uL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3 Result: Not Done: Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 3 | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 4.44 | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 4.00 High 5.40 Unit /uL | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 5 dentifier: Test:: Platelets_ PX5 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|--|---------------|
| | | | Result:: 129 Not Done:: Lab Normal Range: <i>Low</i> 150 <i>High</i> 350 <i>Unit</i> /uL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Platelets_PX5 Result: Not Done: Lab Normal Range: : | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 5 | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Platelets_PX5 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 129 | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Low 150 High 350 Unit /uL | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_PX7 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|---|---------------|
| | | | Result:: 6.28 Not Done:: Lab Normal Range: <i>Low</i> 3.90 <i>High</i> 12.70 <i>Unit</i> /uL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes _PX7 Result: Not Done: Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 7 | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 6.28 | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 3.90 High 12.70 Unit /uL | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined 608 Identifier: Test:: Neutrophils _PX608 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|---|---------------|
| | | | Result:: 4.4 Not Done:: Lab Normal Range: <i>Low</i> 1.8 <i>High</i> 7.7 <i>Unit</i> /uL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Neutrophils_PX608 Result:: Not Done:: Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 608 | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Neutrophils_PX608 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 4.4 | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 1.8 <i>High</i> 7.7 <i>Unit</i> /uL | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Identifier: 609 Test:: Eosinophils_PX609 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|---|---------------|
| | | | Result:: 0.0 Not Done:: Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 0.5 <i>Unit</i> /uL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Eosinophils_PX609 Result: Not Done: Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 609 | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Eosinophils_PX609 | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 0.0 | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Low 0.0 High 0.5 Unit /uL | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_PX612 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|---|---------------|
| | | | Result:: 0.5 Not Done:: Lab Normal Range: <i>Low</i> 0.3 <i>High</i> 1.0 <i>Unit</i> /uL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Monocytes_PX612 Result: Not Done: Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 612 | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Monocytes_PX612 | Initial Entry |

5.h Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.5 | Initial Entry |

5.h LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 0.3 High 1.0 Unit /uL | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined 610 Identifier: Test:: Basophils_ PX610 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|---------------------------|---|---------------|
| | | | Result:: 0.01 Not Done:: Lab Normal Range: <i>Low</i> 0.0 <i>High</i> 0.20 <i>Unit</i> /uL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Basophils_PX610 Result: Not Done: Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 610 | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Basophils_PX610 | Initial Entry |

5.i Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 0.01 | Initial Entry |

5.i LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 0.0 <i>High</i> 0.20 <i>Unit</i> /uL | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Define 611 d Identifier: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|---|-----------------|------------------------------|---|---------------|
| | | | Test:: Lymphocytes _PX611 Result:: 1.3 Not Done:: Lab Normal Range: <i>Low</i> 1.0 <i>High</i> 4.8 <i>Unit</i> /uL | |
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Sponsor-Defined Identifier: Test:: Lymphocytes _PX611 Result:: Not Done:: Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 611 | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:20:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Lymphocytes_PX611 | Initial Entry |

5.j Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 1.3 | Initial Entry |

5.j LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:26:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 1.0 <i>High</i> 4.8 <i>Unit</i> /uL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: HEMATOLOGY | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: St. Tammany Parish Hospital 1202 S Tyler St. Covington, LA 70433 | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/4/2021 | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-----------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLOOD | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 1 Test:: Hemoglobin _PX1 Result:: 13.2 Not Done:: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Lab Normal Range <i>Low</i> : 12.0 <i>High</i> 16.0 <i>Unit</i> g/dL | |
|--|--|--|--|--|

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Hemoglobin_PX1 | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 13.2 | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 12.0 <i>High</i> 16.0 <i>Unit</i> g/dL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Id 2 entifier: Test:: Hematocrit_ PX2 Result:: 38.2 Not Done:: Lab Normal Range <i>Low</i> : 37.0 <i>High</i> 48.5 <i>Unit</i> g/dL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 2 | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 38.2 | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 37.0 High 48.5 Unit g/dL | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 3 dentifier: Test:: Erythrocytes _PX3 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 4.15 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 4.00 |
| | | | | <i>High</i> |
| | | | | 5.40 |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 3 | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 4.15 | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 4.00 High 5.40 Unit /uL | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Platelets_P X5 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 135 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 150 | |
| | | | <i>High</i> | |
| | | | 350 | |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Platelets_PX5 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 135 | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 150 High 350 Unit /uL | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 7 entifier: Test:: Leukocytes_ PX7 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 5.24 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 3.90 |
| | | | | <i>High</i> |
| | | | | 12.70 |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Status: Data Complete

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Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 7 | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 5.24 | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 3.90 High 12.70 Unit /uL | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 608 identifier: Test:: Neutrophils_ PX608 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 3.3 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 1.8 | |
| | | | <i>High</i> | |
| | | | 7.7 | |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 608 | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Neutrophils_PX608 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 3.3 | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 1.8 High 7.7 Unit /uL | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 609 identifier: Test:: Eosinophils_ PX609 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 0.0 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 0.0 | |
| | | | <i>High</i> | |
| | | | 0.5 | |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 609 | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Eosinophils_PX609 | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.0 | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 0.0 High 0.5 Unit /uL | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 612 identifier: Test:: Monocytes_P X612 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 0.6 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | e: 0.3 | |
| | | | <i>High</i> | |
| | | | 1.0 | |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 612 | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Monocytes_PX612 | Initial Entry |

5.h Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 0.6 | Initial Entry |

5.h LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Low 0.3 High 1.0 Unit /uL | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined I 610 dentifier: Test:: Basophils_P X610 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 0.00 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 0.00 |
| | | | | <i>High</i> |
| | | | | 0.20 |
| | | | | <i>Unit</i> |
| | | | | /uL |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 610 | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Basophils_PX610 | Initial Entry |

5.i Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 0.00 | Initial Entry |

5.i LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 0.00 High 0.20 Unit /uL | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined 611 Identifier: Test:: Lymphocytes_ PX611 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

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Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 1.2 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 1.0 | |
| | | | <i>High</i> | |
| | | | 4.8 | |
| | | | <i>Unit</i> | |
| | | | /uL | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 611 | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Lymphocytes_PX611 | Initial Entry |

5.j Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 1.2 | Initial Entry |

5.j LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:32:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> <i>Low</i> 1.0 <i>High</i> 4.8 <i>Unit</i> /uL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: HEMATOLOGY | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: St. Tammany Parish Hospital 1202 S Tyler St Covington, LA 70121 | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/5/2021 | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BLOOD | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined I 1 dentifier: Test:: Hemoglobin _PX1 Result:: 12.7 Not Done:: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|--|--|
| | | | Lab Normal Range <i>Low</i> : 12.0 <i>High</i> 16.0 <i>Unit</i> g/dL | |
|--|--|--|--|--|

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 1 | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Hemoglobin_PX1 | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 12.7 | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: <i>Low</i> 12.0 <i>High</i> 16.0 <i>Unit</i> g/dL | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Id 2 entifier: Test:: Hematocrit_ PX2 Result:: 37.5 Not Done:: Lab Normal Range <i>Low</i> : 37.0 <i>High</i> 48.5 <i>Unit</i> % | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 2 | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Hematocrit_PX2 | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 37.5 | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 37.0 High 48.5 Unit % | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 3 dentifier: Test:: Erythrocytes _PX3 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 4.03 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 4.00 |
| | | | | <i>High</i> |
| | | | | 5.40 |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 3 | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Erythrocytes_PX3 | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 4.03 | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 4.00 High 5.40 Unit /uL | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Platelets_P X5 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 118 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 150 | |
| | | | <i>High</i> | |
| | | | 350 | |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 5 | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Platelets_PX5 | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 118 | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 150 High 350 Unit /uL | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined Id 7 entifier: Test:: Leukocytes_PX7 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|------------------------------------|-------------|
| | | | Result:: 5.11 | |
| | | | Not Done:: | |
| | | | Lab Normal Range <i>Low</i> | |
| | | | : | 3.90 |
| | | | | <i>High</i> |
| | | | | 12.70 |
| | | | <i>Unit</i> | |
| | | | /uL | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 7 | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Leukocytes_PX7 | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 5.11 | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 3.90 High 12.70 Unit /uL | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 608 identifier: Test:: Neutrophils_ PX608 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|--|--|-------------------------------------|--|
| | | | Result:: 3.2 | |
| | | | Not Done:: | |
| | | | Lab Normal Range: <i>Low</i> | |
| | | | 1.8 | |
| | | | <i>High</i> | |
| | | | 7.7 | |
| | | | <i>Unit</i> | |
| | | | /uL | |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 608 | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Neutrophils_PX608 | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> 3.2 | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Low 1.8 High 7.7 Unit /uL | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 609 identifier: Test:: Eosinophils_ PX609 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

| | | | |
|--|--|--|---|
| | | | Result:: Not Done:: NOT DONE Lab Normal Range: |
|--|--|--|---|

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 609 | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Eosinophils_PX609 | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NOT DONE | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_PX612 Result:: Not Done:: NOT DONE Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 612 | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Monocytes_PX612 | Initial Entry |

5.h Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: NOT DONE | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sponsor-Defined Id 610 entifier: Test:: Basophils_P X610 Result:: Not Done:: NOT DONE Lab Normal Range : | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 610 | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Basophils_PX610 | Initial Entry |

5.i Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> NOT DONE | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> Sponsor-Defined I 611 dentifier: Test:: Lymphocytes _PX611 Result:: Not Done:: NOT DONE Lab Normal Range: | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 611 | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> Lymphocytes_PX611 | Initial Entry |

5.j Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------------|---------------|
| Feb-05-2021 14:34:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | <u>Data Entry:</u> NOT DONE | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Feb/01/2021

Form Version: 21-Aug-2020 02:50

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-02-2021 08:55:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/01/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-02-2021 08:55:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/2/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:55:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Record Identifier:: 1 Systolic:: 107 Diastolic:: 72 Respiratory Rate in respirations/minute: 20 Heart Rate in beats/minute: 114 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-02-2021 08:55:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 1 | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-02-2021 08:55:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 107 | Initial Entry |

2.a Diastolic:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-02-2021 08:55:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 72 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/01/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

2.a Respiratory Rate in respirations/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-02-2021 08:55:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 20 | Initial Entry |

2.a Heart Rate in beats/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------|---------------|
| Feb-02-2021 08:55:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 114 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-04-2021 17:33:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-04-2021 17:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-04-2021 17:33:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/3/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---|---------------|
| Feb-04-2021 17:33:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Record Identifier:: 1 Systolic:: 10 8 Diastolic:: 65 Respiratory Rate in respir 17 ations/minute: Heart Rate in beats/minut 68 e: | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-04-2021 17:33:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 1 | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|---------------------------|---------------|
| Feb-04-2021 17:33:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 108 | Initial Entry |

2.a Diastolic:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--------------------------|---------------|
| Feb-04-2021 17:33:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 65 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

2.a Respiratory Rate in respirations/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-04-2021 17:33:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 17 | Initial Entry |

2.a Heart Rate in beats/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-04-2021 17:33:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 68 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Feb-04-2021 17:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/4/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-04-2021 17:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Record Identifier:: 1 Systolic:: 116 Diastolic:: 58 Respiratory Rate in respir 16 ations/minute: Heart Rate in beats/minut 78 e: | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-------------------------|---------------|
| Feb-04-2021 17:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 1 | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------|---------------|
| Feb-04-2021 17:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 116 | Initial Entry |

2.a Diastolic:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------|--------------------------|
| Feb-10-2021 05:11:30 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History
on Feb/01/2021**Form Version:** 14-Jan-2021 02:17**Form Status:** Data Complete**Site No:** 1147**Site Name:** (1147) Ochsner Health System**Subject No:** 11471230**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:56

| | | | | |
|---|-----------------|------------------------------|--------------------------|--|
| Time (US & Canada) | | | | |
| Feb-09-2021 13:52:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | Per PI assessment, the diastolic value of 58 is non-clinically significant |
| Feb-09-2021 12:47:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | Response does not satisfy query |
| Feb-09-2021 09:43:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | NCS per PI |
| Feb-05-2021 03:50:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | DM: Please review and confirm if this value is clinically significant or not. |
| Feb-04-2021 17:34:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | Value is correct. |
| Feb-04-2021 17:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Diastolic BP 58 is outside of Normal Range 60 - 90. |
| Feb-04-2021 17:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 58 | Initial Entry |

2.a Respiratory Rate in respirations/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------|---------------|
| Feb-04-2021 17:34:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 16 | Initial Entry |

2.a Heart Rate in beats/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------|--------------------------|---------------|
| Feb-04-2021 17:34:17 (UTC-06:00) Central | ACV0PFEINFP6000 | James McMullen | Data Entry: 78 | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

Time (US & Canada)

(b) (4)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Feb/01/2021

Form Version: 21-Aug-2020 02:51

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-02-2021 08:55:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-02-2021 08:55:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/2/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-02-2021 08:55:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Record Identifier:: 1 Oxygen Saturation: 91.0 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-02-2021 08:55:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 1 | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-02-2021 08:55:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 91.0 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-04-2021 17:34:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Feb/01/2021

Form Version: 14-Jan-2021 02:17

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-04-2021 17:35:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|---------------|
| Feb-04-2021 17:34:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/3/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|--|---------------|
| Feb-04-2021 17:34:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Record Identifier:: 1 Oxygen Saturation: 98.0 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|-------------------------|---------------|
| Feb-04-2021 17:34:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 1 | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------|---------------|
| Feb-04-2021 17:34:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 98.0 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021 **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 14-Jan-2021 02:17

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Feb-04-2021 17:35:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/4/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-04-2021 17:35:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Record Identifier:: 1 Oxygen Saturation: 95.0 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-------------------------|---------------|
| Feb-04-2021 17:35:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 1 | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------|---------------|
| Feb-04-2021 17:35:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: 95.0 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Feb/01/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date Time of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-04-2021 16:58:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

2. Arterial Blood Gases PaO2 (mmHg):

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-04-2021 16:58:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

3. FiO2 (Fraction of Inhaled Oxygen):

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-04-2021 16:58:17 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. What is the medication identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------------|---------------|
| Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------------|---------------|
| Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------------|---------------|
| Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

4. Medication:

Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------------|---------------|
| Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------------|---------------|
| Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Feb/01/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

6. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Feb-04-2021 17:02:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Not Done | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Audit Trail
on Feb/01/2021

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------|--------|
| Feb-02-2021 08:57:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Feb/01/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Feb-02-2021 08:57:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/2/2021 | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------|---------------|
| Feb-02-2021 08:57:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: CHEST | Initial Entry |

3. Type of Imaging Exam:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------|---------------|
| Feb-02-2021 08:57:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: X-RAY | Initial Entry |

4. Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Feb-02-2021 08:57:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> Patchy infiltrates bilateral bases of lung, no CM | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled Visit on Mar/03/2021

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Mar-03-2021 15:11:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Mar/3/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--------------------------------|---------------|
| Mar-03-2021 15:11:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: COVID_A1 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/03/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-03-2021 16:18:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Mar-03-2021 16:18:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---|
| Mar-04-2021 06:20:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-04-2021 05:10:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-03-2021 16:18:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-03-2021 16:18:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES Date of Collection: Mar/3/2021 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/03/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-04-2021 06:20:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BRZXNM | Initial Entry |

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-04-2021 06:20:29 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BRZXNM | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-04-2021 07:02:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BRZXP1 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-04-2021 07:02:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BRZXP1 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Mar-04-2021 07:10:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sample ID: BR7X7W | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-04-2021 07:10:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> BR7X7W | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Mar/03/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-04-2021 07:10:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BR7X7X | Initial Entry |

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-04-2021 07:10:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BR7X7X | Initial Entry |

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|-----------------------------------|---------------|
| Oct-30-2020 11:19:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Fredrick Okwori (b) (4) | Data Entry: Oct/30/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------------|---------------|
| Oct-30-2020 11:19:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---------------------------------|---------------|
| Oct-30-2020 11:19:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Fredrick Okwori (b) (4) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Feb-18-2021 10:44:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Dec/22/2020 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** Potential ReVax Initial Contact -
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1147**Subject No:** 11471230**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56[Back to Form](#)***1. Select appropriate response - Is participant willing to return for Vaccination 3?***

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---|
| Feb-18-2021 10:45:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-18-2021 10:44:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date. |
| Feb-18-2021 10:44:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per other protocol allowance(s) and confirmed to have received only placebo at Vaccination 1/2 | Initial Entry |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|-----------------------------------|---------------|
| Feb-18-2021 10:45:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Feb/15/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Feb-18-2021 10:45:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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I. Date of Visit

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------------|----------------------------------|--|
| Mar-04-2021 12:38:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-04-2021 09:33:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | Subject was temporarily delayed. Blood, nasal swab and pregnancy test not completed. |
| Mar-04-2021 09:15:56 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: Kindly review and complete 'Immunogenicity, Pregnancy test and Nasal Swab forms' at this visit. Thank you. |
| Mar-03-2021 16:16:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Mar/3/2021 | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (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: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---|---------------|
| Mar-03-2021 16:16:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: OBTAINED Date Written Consent Obtained Mar/3/2021 | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION
- eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|----------------------------------|---------------|
| Mar-03-2021 16:17:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Mar/3/2021 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Mar-03-2021 16:17:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|---------------------------------|---------------|
| Mar-03-2021 16:17:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: COMPLETED | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Incomplete, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Mar-03-2021 16:17:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: YES Date of First Delay: Feb/3/2021 Reason(s) for Temporary Delay of Vaccination RECENT SYSTEMIC COR TICOSTEROID TREATME NT | Initial Entry |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

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1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Oct-30-2020 11:19:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-09-2020 16:39:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Sep-09-2020 16:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SCREENED | Initial Entry |

2. Subject Status Date

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|--|
| Mar-12-2021 05:56:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | SAE RECON:Per confirmation The central lab test result is Negative, SAE report valid'. Please add Acute hypoxemic respiratory failure event in AE CRF. |
| Mar-12-2021 05:55:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Opened | SAE RECON:Per confirmation The central lab test result is Negative, SAE report valid'. Please add COVID-19 event in AE CRF. |
| Mar-10-2021 23:31:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Reissued:Candidate | For Clinical review |
| Mar-10-2021 23:31:40 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Candidate | For Clinical review |

090177e196ae3d78\Final\Final On: 01-Apr-2021 04:34 (GMT)

Header Text: c4591001**Visit:** Subject Status - Unscheduled**Form Version:** 22-Apr-2020 21:03**Site No:** 1147**Subject No:** 11471230**Generated By:** (b) (4)**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Status:** Data Complete, Queries, Verified**Site Name:** (1147) Ochsner Health System**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:56

| | | | | |
|--|-----------------|------------------------------|-----------------------------------|---|
| Mar-10-2021 08:15:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 1: Answered | Per protocol, COVID Illness is to be only captured in the COVID Illness CRFs. Please advise if it should also be captured in AE CRF |
| Mar-10-2021 08:15:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Query 2: Answered | Per protocol, COVID Illness is to be only captured in the COVID Illness CRFs. Please advise if it should also be captured in AE CRF |
| Mar-10-2021 03:33:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 2: Opened | SAE RECON:AER#2021109068 COVID-19 (onset date:02Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Mar-10-2021 03:32:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | SAE RECON:AER#2021109068 Acute hypoxemic respiratory failure (onset date:02Feb2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form. |
| Oct-30-2020 11:19:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Oct/30/2020 | Initial Entry |
| Sep-09-2020 16:39:36 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/9/2020 | Initial Entry |

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1147

Subject No: 11471230

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Queries, Verified

Site Name: (1147) Ochsner Health System

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 11:56

| | | | | |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Sep-09-2020 16:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/9/2020 | Initial Entry |
|--|-----------------|-------------------------|----------------------------------|---------------|

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Verified

Site No: 1147

Site Name: (1147) Ochsner Health System

Subject No: 11471230

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:56

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I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|------------------------------|--|---------------|
| Nov-09-2020 13:44:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | James McMullen (b) (4) | Data Entry: Click Here to Enable | Initial Entry |