

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Informed Consent

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

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 06-Jul-2020 21:55

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DEMOGRAPHY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Demography

| | | |
|----|---------------------------------|--|
| 1. | Subject ID | [11161160] |
| 2. | Birth Date: | (b) (6)/1972 |
| 3. | Sex: | MALE |
| 4. | Ethnicity: | NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN |
| 5. | Race: (Check X all that apply): | WHITE |
| 6. | Racial Designation: | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Form Comments

Medical History Details

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

Vital Signs

| | | |
|----|------------------|------------|
| 1. | Date: | Sep/9/2020 |
| 2. | Weight: | [205.0] |
| 3. | Unit: | LB |
| 4. | Height: | [73.0] |
| 5. | Unit: | in |
| 6. | Body Mass Index: | [27.0] |

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 7.a | Record Identifier: | 1 |
| | Temperature: | [97.6] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition

| | | |
|----|-----------------------|------------|
| 1. | Randomization Date : | Sep/9/2020 |
| 2. | Randomization Number: | [84922] |
| 3. | Randomization Group: | [] |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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 | [BN65G5] |
| 5.b | Sample ID | [BN65G6] |
| 5.c | Sample ID | [BLBFJ3] |
| 5.d | Sample ID | [BLBFJ4] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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 | [BN65PS] |
|-----|-----------|----------|

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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 09:48 |
| 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 |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Sep/28/2020 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|-------------|
| 2.a | Record Identifier: | 1 |
| | Temperature: | [98.3] |
| | Unit: | F |
| | Temperature Location: | ORAL CAVITY |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BP4159] |
|-----|-----------|----------|

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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/28/2020 15:55 |
| 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 |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Oct/26/2020 |
| 2. | Erroneous Visit | |

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Oct/26/2020 |
| 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 | [BP412H] |
| 5.b | Sample ID | [BP412G] |
| 5.c | Sample ID | [BNNRVJ] |
| 5.d | Sample ID | [BNNRVK] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET
on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

| | | |
|----|-----------------|-------------|
| 1. | Date of Visit | Jan/13/2021 |
| 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 Jan/13/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

Signs and Symptoms

| | | |
|----|--------------------------------|-------------|
| 1. | Date of Assessment: | Jan/13/2021 |
| 2. | Date of First Symptom Started: | Jan/8/2021 |
| 3. | Symptoms Ongoing? | YES |

Symptoms

| | | |
|-----|----------------------|--------------------------------------|
| 4.a | Symptoms: | FEVER |
| | Was symptom present? | NO |
| 4.b | Symptoms: | NEW OR INCREASED COUGH |
| | Was symptom present? | YES |
| 4.c | Symptoms: | NEW OR INCREASED SHORTNESS OF BREATH |
| | Was symptom present? | NO |
| 4.d | Symptoms: | CHILLS |
| | Was symptom present? | 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? | NO |
| 4.h | Symptoms: | DIARRHEA |
| | Was symptom present? | NO |
| 4.i | Symptoms: | VOMITING |
| | Was symptom present? | NO |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Jan/13/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Symptoms - Other

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | Date of Collection | Specimen Type | Specimen Collection Location | Assay Code and Description | Device Type | Form Instance |
|----|--------------------|------------------|------------------------------|--|----------------------------|---------------------------------|
| 1. | Jan/13/2021 | SWABBED MATERIAL | NASOPHARYNX | SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2 | SARS-COV-2 DIAGNOSTIC TEST | Repeating Pages |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN
on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Microbiology Specimen

| | | |
|----|-------------------------------|--|
| 1. | Actual Date of Collection: | Jan/13/2021 |
| 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] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Jan/13/2021 |
| 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 | [BP40XJ] |
|-----|-----------|----------|

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION
on Jan/13/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58**eCRF Audit Trail History****Health Care Utilization**

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

Health Care Utilization Other

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

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Respiratory Treatment

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS
on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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/13/2021 |
| 3. | Toxicity Grade: | 1 |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 21-Aug-2020 02:49

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/13/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Lab Chemistry Details

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

Lab Result

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/13/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/13/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Jan/13/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Blood Urea Nitrogen_PX47 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.g | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Creatinine_PX48 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 21-Aug-2020 02:51

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Laboratory Data Hematology

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

Lab Result

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | |
|-----|-------------|--|--------------------------|
| 5.b | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Hematocrit_PX2 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.c | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Erythrocytes_PX3 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | |
|-----|-------------|--|--------------------------|
| 5.d | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Platelets_PX5 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.e | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Leukocytes_PX7 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | |
|-----|-------------|--|--------------------------|
| 5.f | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Neutrophils_PX608 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.g | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Eosinophils_PX609 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | |
|-----|-------------|--|--------------------------|
| 5 h | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Monocytes_PX612 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |
| 5.i | Sponsor ID: | Not Done _____ [] | Comments |
| | Test: | Basophils_PX610 | |
| | Result: | Not Done _____ [] | Comments |
| | Not Done: | Not Done _____ | Comments |
| | LNMT | Not Done _____ Low [] High [] Unit | Comments |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 21-Aug-2020 02:50

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | Date: | Vital Signs Details | | | Form Instance |
|----|-------------|---------------------------|------------------|-------------------|---------------------------------|
| 1. | Jan/13/2021 | Record Identifier: | Systolic: | Diastolic: | Repeating Pages |
| | | 1 | 129 | 78 | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID
on Jan/13/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Jan/13/2021 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|--|-------|
| 2.a | Record Identifier: | 1 |
| | Systolic: | [129] |
| | Diastolic: | [78] |
| | Respiratory Rate in respirations/minute: | [16] |
| | Heart Rate in beats/minute: | [89] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | Date: | Vital Signs Details | | Form Instance |
|----|-------------|---------------------------|--------------------------|---------------------------------|
| 1. | Jan/13/2021 | Record Identifier: | Oxygen Saturation | Repeating Pages |
| | | 1 | 93.0 | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR
on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

Vital Signs

| | | |
|----|-------|-------------|
| 1. | Date: | Jan/13/2021 |
|----|-------|-------------|

Vital Signs Details

| | | |
|-----|-----------------------|--------|
| 2.a | Record Identifier: | 1 |
| | SPO2 Pulse Oximetry % | [93.0] |

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS
on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | 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 Jan/13/2021

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

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 |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Imaging

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** DATE OF VISIT - ILLNESS CONVALESCENT
Visit on Feb/17/2021

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

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

COVID-19 Illness Visit

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY
Visit on Feb/17/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|---|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Feb/17/2021 |
| 4. | If no sample was collected or sample was not collected according to protocol, please provide reason: | [] |

Aliquot

Please enter barcode for each aliquot.

| | | |
|-----|-----------|----------|
| 5.a | Sample ID | [BRJ01K] |
| 5.b | Sample ID | [BRJ01L] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Disposition - Treatment

| | | |
|----|--|-------------|
| 1. | Date of Completion/Discontinuation/Death : | Oct/26/2020 |
| 2. | Phase of Disposition: | VACCINATION |
| 3. | Status: | COMPLETED |
| 4. | Specify Status: | [] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

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

COVID-19 Repeat Swab

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | Category | AE Identifier | Adverse Event | Start Date | Is the Adverse Event Still Ongoing | Form Instance |
|------------|----------|---------------|---------------|------------|------------------------------------|---------------------------------|
| 1. DELETED | | | | | | Repeating Pages |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

[Back to Form](#)
[eCRF Audit Trail History](#)
[Form Audit Trail](#)

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? | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

| | | |
|-----|--|-----|
| 12. | Was a Non-Drug Treatment given? | |
| 13. | What was the outcome of this adverse event?: | |
| 14. | Did the adverse event cause the subject to be discontinued from the study? | |
| 15. | Serious Adverse Event Number: For Pfizer Use Only | [] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | 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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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 | [] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | 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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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: | // |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | 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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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? | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | 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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| # | 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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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? | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[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 local/national recommendations 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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Treatment Unblinded

| | | |
|----|--------------------------------|---|
| 1. | Date Treatment Unblinded : | Feb/26/2021 |
| 2. | Primary Reason for Unblinding: | ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION |

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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

Disposition - Screening for Further Vaccination

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | SERUM |
| 3. | Sample Collected? | YES Date of Collection: Mar/1/2021 |
| 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 | [BRJ04D] |
|-----|-----------|----------|

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

Electronic Sample Tracking

| | | |
|----|--|--|
| 1. | Data Origin | SITE |
| 2. | Sample Type | NASAL_SWAB |
| 3. | Sample Collected? | YES Date of Collection: Mar/1/2021 |
| 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 | [BRJ05X] |
| 5.b | Sample ID | [BRJ05Y] |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

eCRF Audit Trail History

| Vaccination | | |
|--------------------|---|------------------|
| 1. | Was there a temporary delay of vaccination? | NO |
| 2. | Treatment Name | [BNT162b2] |
| 3. | Formulation: | INJECTION |
| 4. | Dose Date Time: | Mar/1/2021 09:32 |
| 5. | Anatomical Location: | DELTOID MUSCLE |
| 6. | Body Side: | LEFT |
| 7. | Route: | INTRAMUSCULAR |
| 8. | Actual Dose: | [30.0] |
| 9. | Unit: | ug |
| 10. | Timeframe Subject Was Observed | 30 MINUTES |
| 11. | Was the subject observed for at least the protocol specified observation period after investigational product administration? | YES |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VACCINATION

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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? | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Subject Status

| | | |
|----|---------------------|-------------|
| 1. | Subject Status | FOLLOW-UP |
| 2. | Subject Status Date | Oct/26/2020 |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Audit Trail](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|---------------|-------------------|---|------|--------|
| Paul Matherne | Approved | Mar-12-2021 12:12:16 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

Affidavit:

By my dated signature below, I, PaulMatherne, 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.

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 30-Jul-2020 21:29

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|----------------------------|----------------|
| Form | Sep-09-2020 10:30:43 (UTC-06:00) Central Time (US & Canada) | Heather Lambert (b) (4) | Not Applicable |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|----------------------------|----------------|
| Form | Sep-09-2020 10:31:21 (UTC-06:00) Central Time (US & Canada) | Heather Lambert (b) (4) | Not Applicable |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| Form | Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 1 | Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 2 | Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 3 | Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 4 | Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 | Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 6 | Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| Form | Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 1 | Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 2 | Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 3 | Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - Comments
on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 4 | Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| Form | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 1 | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 2 | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 3 | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 4 | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.a | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.a | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.a | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.a | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.b | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

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Site Name: (1116) MedPharmics, LLC

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.b | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

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Site Name: (1116) MedPharmics, LLC

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.b | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site Name: (1116) MedPharmics, LLC

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.b | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.c | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.c | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.c | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.c | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.d | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.d | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.d | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.d | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.e | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.e | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.e | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.e | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 f | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 f | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 f | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 f | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.g | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.g | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.g | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.g | Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology -
on Jan/13/2021 Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| Form | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 1 | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 2 | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 3 | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 4 | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.a | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.a | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.a | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|-----------------------------------|----------|
| 5.a | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.b | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.b | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.b | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|-----------------------------------|----------|
| 5.b | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology -
on Jan/13/2021 Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|-----------------------------------|----------|
| 5.c | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

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Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.c | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.c | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.c | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.d | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.d | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.d | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.d | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.e | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.e | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.e | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 f | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 f | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 f | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 f | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.g | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.g | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.g | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
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Form Version: 21-Aug-2020 02:51

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 h | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Subject No: 11161160

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 h | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5 h | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology -
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Form Version: 21-Aug-2020 02:51

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|-----------------------------------|----------|
| 5 h | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

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Form Version: 21-Aug-2020 02:51

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Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.i | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.i | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.i | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Form Version: 21-Aug-2020 02:51

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Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.i | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

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Form Version: 21-Aug-2020 02:51

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 5.j | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology -
on Jan/13/2021 Comments

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|-----------------------------------|----------|
| 5.j | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |

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Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
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on Jan/13/2021 Comments

Form Version: 21-Aug-2020 02:51

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Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|-----------------------------------|----------|
| 5.j | Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [REDACTED] | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| Form | Jan-26-2021 10:32:07 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|--|-----------------------------------|----------|
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090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 2 | Jan-26-2021 10:32:07 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 3 | Jan-26-2021 10:32:07 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| Form | Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 1 | Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|-----------------------------------|----------|
| 2 | Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 3 | Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 4 | Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|-----------------------------------|----------|
| 5 | Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) [Redacted] | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 6 | Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| Form | Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 1 | Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 2 | Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 3 | Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Done |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** IMAGING - Comments
on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|---------------------|----------|
| 4 | Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | 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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Mar-04-2021 15:28:20 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| Form | Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| Form | Mar-04-2021 15:28:32 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 1 | Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 1 | Mar-04-2021 15:28:32 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 2 | Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 2 | Mar-04-2021 15:28:32 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 3 | Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 3 | Mar-04-2021 15:28:32 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Item | Date | User | Comment |
|------|---|------------------|----------------|
| 4 | Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | |
| 4 | Mar-04-2021 15:28:32 (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Not Applicable |

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

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

- CRF_Sign

| Name | Signature Meaning | Date | Type | Action |
|---------------|-------------------|---|------|--------|
| Paul Matherne | Approved | Mar-12-2021 12:12:16 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Paul Matherne | Approved | Mar-04-2021 15:40:46 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Jan-26-2021 10:23:53 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|---------------|----------|---|------|--------|
| Paul Matherne | Approved | Jan-21-2021 18:13:22 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

Affidavit:

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

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

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

| | | | | |
|---------|-----|---|--|-----------------------------------|
| (b) (6) | N/A | Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | | Edit - All signatures invalidated |
|---------|-----|---|--|-----------------------------------|

Affidavit:

N/A

| | | | | |
|---------------|----------|---|------|--------|
| Paul Matherne | Approved | Nov-05-2020 16:43:35 (UTC-06:00) Central Time (US & Canada) | BOOK | Signed |
|---------------|----------|---|------|--------|

Affidavit:

By my dated signature below, I, PaulMatherne, 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.

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 30-Jul-2020 21:29

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: COHORT_SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Select appropriate response - Protocol version

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|-----------------------------------|---------------|
| Sep-09-2020 10:28:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (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 10:28:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: STAGE 3 COHORTS | Initial Entry |

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---|---------------|
| Sep-09-2020 10:28:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (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: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Subject ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|-----------------------------------|
| Sep-09-2020 10:28:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 11161160 | Item copied from previous form |

2. Birth Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|------------------------------------|------------------|
| Sep-09-2020 10:28:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: (b) (6)/1972 | Enrollment Entry |

3. Sex:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|----------------------------|---------------|
| Sep-09-2020 10:30:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: MALE | Initial Entry |

4. Ethnicity:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|--|---------------|
| Sep-09-2020 10:30:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (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 10:30:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: WHITE | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|----------------------------------|---------------|
| Sep-09-2020 10:30:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: Sep/9/2020 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Completion/Discontinuation/Death

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|----------------------------------|---------------|
| Sep-09-2020 10:31:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: Sep/9/2020 | Initial Entry |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Sep-09-2020 10:31:10 (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 10:31:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: COMPLETED | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|----------------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: Sep/9/2020 | Initial Entry |

2. Weight:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|-----------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: 205.0 | Initial Entry |

3. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|--------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: LB | Initial Entry |

4. Height:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|----------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: 73.0 | Initial Entry |

5. Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|--------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: in | Initial Entry |

6. Body Mass Index:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|-----------|--------------------|---------------|
| Sep-09-2020 10:31:52 | ACV0PFEINFP6000 | auto calc | Data Entry: | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|--|--|------------|------|--|
| (UTC-06:00) Central Time (US & Canada) | | (autocalc) | 27.0 | |
|--|--|------------|------|--|

7.a

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------------|--|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: Record Identifier 1 :: Temperature: 97.6 Temperature Unit: Temperature Location: ORAL CAVITY | Initial Entry |

7.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------------|-------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: 1 | Initial Entry |

7.a Temperature:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------------|----------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: 97.6 | Initial Entry |

7.a Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------------|-------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: F | Initial Entry |

7.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-----------------|-----------------------------------|---------------|
| Sep-09-2020 10:31:52 (UTC-06:00) Central | ACV0PFEINFP6000 | Heather Lambert | Data Entry: ORAL CAVITY | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 21-Aug-2020 02:51

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

Time (US & Canada)

(b) (4)

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Randomization Date :

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|----------------------------------|---------------|
| Sep-09-2020 10:32:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: Sep/9/2020 | Initial Entry |

2. Randomization Number:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|-----------------------------|---------------|
| Sep-09-2020 10:32:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: 84922 | Initial Entry |

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-09-2020 10:33:11 (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 10:33:11 (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-09-2020 18:22:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-09-2020 10:33:11 (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 10:33:11 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: YES Date of Collection: Sep/9/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---|---------------|
| Sep-09-2020 18:22:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: Sample ID: BN65G5 | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|------------------------------|---------------|
| Sep-09-2020 18:22:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | <u>Data Entry:</u> BN65G5 | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---|---------------|
| Sep-09-2020 18:22:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | <u>Data Entry:</u> Sample ID: BN65G6 | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|------------------------------|---------------|
| Sep-09-2020 18:22:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | <u>Data Entry:</u> BN65G6 | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---|---------------|
| Sep-09-2020 18:22:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | <u>Data Entry:</u> Sample ID: BLBFJ3 | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|------------------------------|---------------|
| Sep-09-2020 18:22:35 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | <u>Data Entry:</u> BLBFJ3 | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---|---------------|
| Sep-09-2020 18:22:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | <u>Data Entry:</u> Sample ID: BLBFJ4 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|------------------------------|---------------|
| Sep-09-2020 18:22:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: BLBFJ4 | Initial Entry |

Header Text: c4591001**Visit:** V1_DAY1_VAX1_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-09-2020 10:33:20 (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 10:33:20 (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-09-2020 18:23:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-09-2020 10:33:20 (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 10:33:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: YES Date of Collection: Sep/9/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---|---------------|
| Sep-09-2020 18:23:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: Sample ID: BN65PS | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|------------------------------|---------------|
| Sep-09-2020 18:23:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: BN65PS | Initial Entry |

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|--------------------------|---------------|
| Sep-09-2020 10:33:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-09-2020 10:33:39 (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 10:33:39 (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 10:33:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: Sep/9/2020 09:48 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-09-2020 10:33:39 (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 10:33:39 | ACV0PFEINFP6000 | Heather | Data Entry: | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|--|--|--------------------|------|--|
| (UTC-06:00) Central Time (US & Canada) | | Lambert (b) (4) | LEFT | |
|--|--|--------------------|------|--|

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-09-2020 10:33:39 (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 10:33:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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 10:33:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: YES | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Select appropriate response - Reactogenicity diary collection

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------------|---|---------------|
| Sep-09-2020 10:34:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | Heather Lambert (b) (4) | Data Entry: NO - REACTOGENICITY E-D IARY NOT COLLECTED FOR THIS SUBJECT | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-29-2020 15:22:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/28/2020 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-29-2020 16:18:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/28/2020 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-29-2020 16:18:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier: 1 Temperature: 98.3 Temperature Unit: Temperature Location: ORAL CAVITY | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-29-2020 16:18:58 (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 |
|---|-----------------|---------------------|----------------------------|---------------|
| Sep-29-2020 16:18:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 98.3 | Initial Entry |

2.a Unit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Sep-29-2020 16:18:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: F | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 15-Sep-2020 21:54

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

2.a Temperature Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Sep-29-2020 16:18:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ORAL CAVITY | 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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Sep-29-2020 15:22:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Sep-29-2020 15:22:33 (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-29-2020 15:22:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Sep-29-2020 15:22:33 (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. |
| Sep-29-2020 15:22:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Sep/28/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Sep-29-2020 15:22:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP4159 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Sep-29-2020 15:22:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP4159 | Initial Entry |

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Sep-29-2020 16:19:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Sep-29-2020 16:19:18 (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-29-2020 16:19:18 (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-29-2020 16:19:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sep/28/2020 15:55 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Sep-29-2020 16:19:18 (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-29-2020 16:19:18 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|--|--|---------------------|------|--|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | LEFT | |
|--|--|---------------------|------|--|

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Sep-29-2020 16:19:18 (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-29-2020 16:19:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: THE PROTOCOL SPECIFIED OBSERVATION 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-29-2020 16:19:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---|
| Oct-31-2020 08:35:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-30-2020 11:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | Changed data per query |
| Oct-30-2020 04:30:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | DM: The treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please complete treatment disposition CRF and update date of EOT to match date of blood sample collection date at visit 3. |
| Oct-27-2020 17:15:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/26/2020 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (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:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Oct-27-2020 17:16:04 (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-27-2020 17:16:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Oct-27-2020 17:18:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Oct-27-2020 17:16:04 (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-27-2020 17:16:04 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Oct/26/2020 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Oct-27-2020 17:18:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP412H | 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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 17:18:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP412H | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-27-2020 17:18:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP412G | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 17:18:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP412G | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-27-2020 17:19:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNNRVJ | Initial Entry |

5.c Sample ID

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 17:19:10 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNNRVJ | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Oct-27-2020 17:19:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BNNRVK | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Oct-27-2020 17:19:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BNNRVK | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

I. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------|--|
| Mar-01-2021 01:25:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Closed | Response satisfies query |
| Feb-26-2021 10:01:53 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Answered | 17FEB2021 Convalescent visit occurred |
| Feb-17-2021 23:59:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 3: Opened | PDQ: Convalescent visit is missing and 35 days (36) have passed since COVID Illness Visit. If visit occurred record data as a matching CONVA visit; if visit did not occur attempt to schedule visit even if OOW and obtain the CONVA sample else clarify. |
| Jan-26-2021 10:27:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 2: Deleted | Close Auto Query |
| Jan-26-2021 10:23:51 (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. |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|---|-----------------|---------------------------|-----------------------------------|--|
| Jan-26-2021 10:23:51 (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. |
| Jan-26-2021 10:23:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/13/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------|---------------|
| Jan-26-2021 10:23:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: COVID_A | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
on Jan/13/2021 Audit Trail History**Form Version:** 14-Jan-2021 02:23**Form Status:** Data Complete**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Date of Assessment:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/13/2021 | Initial Entry |

2. Date of First Symptom Started:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 | Initial Entry |

3. Symptoms Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: FEVER Symptom Present: NO | Initial Entry |

4.a Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: FEVER | Initial Entry |

4.a Was symptom present?

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |
|--|-----------------|---------------------|--------------------------|---------------|

4.b

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms NEW OR INCREA : SED COUGH Symptom YES Present: | Initial Entry |

4.b Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED COUGH | Initial Entry |

4.b Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: NEW OR INCREASE D SHORTNESS OF BREATH Symptom Present: NO | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
on Jan/13/2021 Audit Trail History

Form Version: 14-Jan-2021 02:23

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.c Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SHORT NESS OF BREATH | Initial Entry |

4.c Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: CHILLS Symptom Present: YES | Initial Entry |

4.d Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: CHILLS | Initial Entry |

4.d Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.e

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom NEW OR INCREAS | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | |
|--------------------|------------------|--|
| Time (US & Canada) | (b) (4), (b) (6) | s: ED MUSCLE PAIN Symptom YES Present: |
|--------------------|------------------|--|

4.e Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED MUSCLE PAIN | Initial Entry |

4.e Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

4.f

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms NEW LOSS OF TASTE OR SMELL Symptom YES Present: | Initial Entry |

4.f Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW LOSS OF TASTE OR SMELL | Initial Entry |

4.f Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-----------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.g

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptom NEW OR INCREAS s: ED SORE THROAT Symptom NO Present: | Initial Entry |

4.g Symptoms:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NEW OR INCREASED SORE T HROAT | Initial Entry |

4.g Was symptom present?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.h

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: DIARRHE A Symptom Present NO : | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

4.h Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: DIARRHEA | Initial Entry |

4.h Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

4.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Symptoms: VOMITIN G Symptom Present NO : | Initial Entry |

4.i Symptoms:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: VOMITING | Initial Entry |

4.i Was symptom present?

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:24:52 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Jan-26-2021 10:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Actual Date of Collection:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 10:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/13/2021 | Initial Entry |

2. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SWABBED MATERIAL | Initial Entry |

3. Specimen Collection Location:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 10:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NASOPHARYNX | Initial Entry |

4. Assay Code and Description:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Jan-26-2021 10:25:37 (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 |
|---|-----------------|-------------------------|--|---------------|
| Jan-26-2021 10:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SARS-COV-2 DIAGNOSTIC TE ST | Initial Entry |

6. Trade Name:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|---------------------|--------------------|---------------|
| Jan-26-2021 10:25:37 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|--|--|------------------|-------|--|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | OTHER | |
|--|--|------------------|-------|--|

7. Test Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: POSITIVE | Initial Entry |

9. Trade Name Other, Specify:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|------------------------------------|---------------|
| Jan-26-2021 10:25:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NALT UNKNOWN | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History
on Jan/13/2021

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Data Origin

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-26-2021 10:25:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------------|---------------|
| Jan-26-2021 10:25:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB_SELF | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:25:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

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

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:25:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COLLECTED IN CLINIC | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History
on Jan/13/2021**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Jan-26-2021 10:27:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Jan-26-2021 10:27:01 (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 |
|---|-----------------|---------------------------|---|---|
| Jan-26-2021 10:33:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Jan-26-2021 10:27:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Jan-26-2021 10:27:01 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Jan/13/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:33:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BP40XJ | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
on Jan/13/2021 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Jan-26-2021 10:33:16 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BP40XJ | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

I.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO | Initial Entry |

I.a Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|----------------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: SPECIALIST | Initial Entry |

I.a Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.b Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: EMERGENCY ROOM | Initial Entry |

1.b Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:28:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO | Initial Entry |
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021**Form Version:** 14-Jan-2021 02:24**Form Status:** Data Complete**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58***1.c Physician or Healthcare Professional:***

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: PRIMARY CARE PHYSICIAN | Initial Entry |

1.c Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:28:02 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.d

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO | Initial Entry |

1.d Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: URGENT CARE | Initial Entry |

1.d Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

1.e

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO | Initial Entry |
|---|-----------------|---------------------|---|---------------|

I.e Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: TELEPHONE CONSULTATION | Initial Entry |

I.e Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

I.f

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Jan/13/2021

Form Version: 14-Jan-2021 02:24

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

1.f Physician or Healthcare Professional:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OTHER | Initial Entry |

1.f Occurrence of Visits or Contacts:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Number of Visits or Contacts:</i> 1 | Initial Entry |

2. Other Type of Practitioner Specify:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COUNTY HEALTH DEPARTM ENT | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:27:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. What is the treatment Identifier?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Concomitant Non-drug Treatment Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

6. Ongoing?

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:27:43 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |
|---|-----------------|---------------------|--------------------------------|---------------|

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Jan-26-2021 10:28:30 (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 |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:28:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES <i>Respiratory Illness Diagnosis:</i> COVID-19 Date of Diagnosis: Jan/13/2021 | Initial Entry |

3. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Jan-26-2021 10:28:30 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Jan/13/2021

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Category of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Subcategory of Clinical Event:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Was a diagnosis obtained?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:28:46 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Jan/13/2021**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY -
eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Lab Panel:**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|--|--|--|--------------------------|----------|
| | | | Not Done:: | Not Done |
| | | | Lab Normal Range: | Not Done |

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:49

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:20 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Lab Panel:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Laboratory Name and Address

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Collection Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Specimen Type:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|--|--|--|-------------------|----------|
| | | | Not Done:: | Not Done |
| | | | Lab Normal Range: | Not Done |

5.a Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.a LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done Test:: Not Done Result:: Not Done Not Done:: Not Done Lab Normal Range: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.b Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.b LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.c Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.c LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.d Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.d LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.e Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.e LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.f

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.f Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.f Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.f Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.f Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.f LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.g Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.g LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.h

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.h Sponsor ID:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h Test:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h Result:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h Not Done:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.h LNMT

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Not Done | Initial Entry |

5.i

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> Sponsor-Defined Identifier: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | | |
|--|--|--|--------------------------|----------|--|
| | | | Test:: | Not Done | |
| | | | Result:: | Not Done | |
| | | | Not Done:: | Not Done | |
| | | | Lab Normal Range: | Not Done | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

5.i Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.i Test:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.i Result:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.i Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.i LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.j

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Jan-26-2021 10:29:42 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | |
|--|------------------|------------------------------------|----------|
| (UTC-06:00) Central Time (US & Canada) | (b) (4), (b) (6) | Sponsor-Defined Identifier: | Not Done |
| | | Test:: | Not Done |
| | | Result:: | Not Done |
| | | Not Done:: | Not Done |
| | | Lab Normal Range: | Not Done |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.j Sponsor ID:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.j Test:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.j Result:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.j Not Done:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5.j LNMT

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:29:42 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail
on Jan/13/2021

Form Version: 21-Aug-2020 02:50

Form Status:

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Jan-26-2021 10:31:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 10:31:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/13/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:31:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Systolic:: 12 9 Diastolic:: 78 Respiratory Rate in respir 16 ations/minute: Heart Rate in beats/minute 89 : | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-------------------------|---------------|
| Jan-26-2021 10:31:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a Systolic:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|---------------|
| Jan-26-2021 10:31:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 129 | Initial Entry |

2.a Diastolic:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:31:21 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 78 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - eCRF Audit Trail History on Jan/13/2021

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | |
|--------------------|------------------|
| Time (US & Canada) | (b) (4), (b) (6) |
|--------------------|------------------|

2.a Respiratory Rate in respirations/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:31:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 16 | Initial Entry |

2.a Heart Rate in beats/minute:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Jan-26-2021 10:31:21 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 89 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status:

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|--------|
| Jan-26-2021 10:31:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail on Jan/13/2021

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-----------------------------------|---------------|
| Jan-26-2021 10:31:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/13/2021 | Initial Entry |

2.a

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------|
| Jan-26-2021 10:31:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Record Identifier:: 1 Oxygen Saturation: 93.0 | Initial Entry |

2.a Record Identifier:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|-------------------------|---------------|
| Jan-26-2021 10:31:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 1 | Initial Entry |

2.a SPO2 Pulse Oximetry %

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|----------------------------|---------------|
| Jan-26-2021 10:31:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: 93.0 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date Time of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Arterial Blood Gases PaO2 (mmHg):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. FiO2 (Fraction of Inhaled Oxygen):

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:07 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit
on Jan/13/2021**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF
Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. What is the medication identifier?**

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Concomitant Medications Pre-specified:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | 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 |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

5. Start Date:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Jan/13/2021

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

6. Ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Jan/13/2021

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

2. Location of Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

3. Type of Imaging Exam:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

4. Assessment:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Jan-26-2021 10:32:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Done | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/17/2021

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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-26-2021 09:46:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/17/2021 | Initial Entry |

3. COVID-19 Illness Visit:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------|---------------|
| Feb-26-2021 09:46:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COVID_A1 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/17/2021**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Feb-26-2021 09:46:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Feb-26-2021 09:46:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SERUM | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|---|
| Feb-26-2021 10:05:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Feb-26-2021 09:46:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Feb-26-2021 09:46:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Feb/17/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-26-2021 10:05:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJ01K | Initial Entry |

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Feb/17/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-26-2021 10:05:47 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRJ01K | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Feb-26-2021 10:06:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJ01L | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Feb-26-2021 10:06:00 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRJ01L | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|-----------------|------------------------|-----------------------------------|--|
| Nov-02-2020 08:58:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Oct-30-2020 11:27:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Oct-30-2020 11:27:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Oct/26/2020 | Initial Entry |
| Oct-28-2020 12:38:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: Please complete the End of Treatment CRF. Per Guidelines, If the Participant receives all vaccinations as per protocol and completes the follow-up visit procedures within the 1-month post vaccination period, report the status as COMPLETED. |

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|--|-----------------|----------------------|-----------------------------------|---------------|
| Oct-30-2020 11:27:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: VACCINATION | Initial Entry |

3. Status:

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

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|---|-----------------|---------------------|---------------------------------|---------------|
| Oct-30-2020 11:27:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |
|---|-----------------|---------------------|---------------------------------|---------------|

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

[Back to Form](#)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------|------------------------|
| Feb-12-2021 16:12:55 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Deleted | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Form Created | |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

[Back to Form](#)

1. Category:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------------------|------------------------|
| Feb-12-2021 16:10:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> ADVERSE EVENT | Initial Entry |

2. AE ID:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-------------------------|------------------------|
| Feb-12-2021 16:10:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | <u>Data Entry:</u> 1 | Initial Entry |

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--------------------------|---|
| Feb-15-2021 15:10:03 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Feb-12-2021 16:10:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Changed Information |
| Feb-12-2021 16:10:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Changed Information |
| Feb-10-2021 09:46:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Reissued:Opened | CLINREQUEST: Per Protocol Section 8.3.7, as the Site has appropriately |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

| | | | | |
|--|-----------------|---------------------|---------------------------------------|--|
| | | | | entered this same AE on the COVID Illness CRF, it is not required to be entered on the AE CRF. Please confirm this AE Record is Not Applicable and update. |
| Feb-09-2021 12:07:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | AE IS RELATED TP THE COVID ILLNESS VISIT 13JAN2021 |
| Jan-27-2021 12:17:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | CLINQUERY: Per CRF Signs and Symptoms of Potential COVID-19, New or Increased Muscle Pain is also listed with the same Start Date (8-Jan-21) as this AE. Please determine if this AE was related to the Potential COVID Illness. Please update or clarify. |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Lower Back Ache | Initial Entry |

4. Start Date Time:

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|--|---------------------|
| Feb-12-2021 16:10:37 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Jan/8/2021 00:00 | Initial Entry |

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

5. Is the adverse event still ongoing?

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------------|
| Feb-12-2021 16:10:48 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Changed Information |
| Feb-11-2021 08:32:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO End Date Time: Jan/10/2021 18:00 | New Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

6. Toxicity Grade:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|-------------------------|---------------------|
| Feb-12-2021 16:10:59 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> 1 | Initial Entry |

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------------|
| Feb-12-2021 16:11:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

| | |
|--------------------|------------------|
| Time (US & Canada) | (b) (4), (b) (6) |
|--------------------|------------------|

8. Is this adverse event the result of a study Medication Error?
If Yes, record the type of medication error on the Medication Error Log.

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------|---------------------|
| Feb-12-2021 16:11:23 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

9. Is this event related to study treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------------|
| Feb-12-2021 16:11:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER <i>If Other, specify:</i> Unknown | Initial Entry |

10. Latest Action Taken with Study Treatment:

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|--------------------------------------|---------------------|
| Feb-12-2021 16:11:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT APPLICABLE | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

11. Was a Concomitant Medication given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---------------------------|------------------------|
| Feb-12-2021 16:11:54 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> YES | Initial Entry |

12. Was a Non-Drug Treatment given?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|------------------------|
| Feb-12-2021 16:12:08 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> NO | Initial Entry |

13. What was the outcome of this adverse event?:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|--|
| Feb-12-2021 16:12:18 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> | Changed Information |
| Feb-12-2021 16:08:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Feb-12-2021 16:08:22 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | <u>Data Entry:</u> RECOVERED/RESOLVED | New Information |
| Feb-11-2021 08:32:26 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | For AE Lower Back Ache: Response to "What was the outcome of this adverse event?" is 'Not Recovered/Not Resolved' but AE |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Incomplete, Data Complete, Deleted

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

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

| | | | | |
|---|-----------------|---------------------|--|---------------------------|
| | | | | End Date/Time is present. |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NOT RECOVERED/NOT RE SOLVED | Initial Entry |

14. Did the adverse event cause the subject to be discontinued from the study?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|------------------------|
| Feb-12-2021 16:12:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Changed Information |
| Jan-11-2021 11:52:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-27-2021 10:54:44 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/26/2021 | Initial Entry |

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit
Trail History

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Select appropriate response - Is participant willing to return for Vaccination 3?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-27-2021 10:54:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Participant is willing to return f or Vaccination 3 Participant is: eligible per local/national rec ommendations and confirme d to have received only place bo at Vaccination 1/2 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date Treatment Unblinded :

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|-----------------------------------|---------------|
| Feb-27-2021 10:54:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Feb/26/2021 | Initial Entry |

2. Primary Reason for Unblinding:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|---|---------------|
| Feb-27-2021 10:54:24 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Date of Visit

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|----------------------------------|--|
| Mar-04-2021 15:29:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-04-2021 15:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Date of Visit is before the Date Written Consent Obtained. Please review and update as appropriate. |
| Mar-04-2021 15:27:28 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/1/2021 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (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: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

I. Consent Was:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|---|--|
| Mar-04-2021 15:29:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Closed | Close Auto Query |
| Mar-04-2021 15:29:13 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Mar/1/2021 | Transcription Error |
| Mar-04-2021 15:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Opened | Date Informed Consent Obtained is not the same as the Date of Visit. Please correct as necessary. |
| Mar-04-2021 15:28:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: OBTAINED Date Written Consent Obtained Mar/3/2021 | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

I. Date of Completion/Discontinuation/Death :

| Date | Location | User | Value | Reason |
|--|---|------------------------|-----------------------------------|--|
| Mar-08-2021 15:14:51 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Mar-08-2021 09:29:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Answered | Initial Entry |
| Mar-08-2021 09:29:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Mar/1/2021 | Initial Entry |
| Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : | Initial Entry |
| Mar-08-2021 06:58:12 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000.InFormAdapter.Discrepancy | DMW QUERY (b) (4) | Query 1: Opened | DMW7625699;Date is not expected to be Unknown or Not Applicable. Please review and update appropriately or clarify |
| Mar-04-2021 15:28:32 (UTC-06:00) Central Time | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry : Not A | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|---------------|--|--|---------------|--|
| (US & Canada) | | | pplica ble | |
|---------------|--|--|---------------|--|

2. Phase of Disposition:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--|---------------|
| Mar-08-2021 09:29:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: REPEAT SCREENING 1 | Initial Entry |
| Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Mar-04-2021 15:28:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

3. Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Mar-08-2021 09:29:06 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: COMPLETED | Initial Entry |
| Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Mar-04-2021 15:28:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

4. Specify Status:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------------------|---------------|
| Mar-08-2021 09:28:49 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |
| Mar-04-2021 15:28:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Not Applicable | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-08-2021 09:29:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|-----------------------------|---------------|
| Mar-08-2021 09:29:32 (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-08-2021 10:40:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Mar-08-2021 09:29:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-08-2021 09:29:32 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/1/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Mar-08-2021 10:40:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJ04D | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-08-2021 10:40:39 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRJ04D | Initial Entry |

Header Text: c4591001**Visit:** V101_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1116**Site Name:** (1116) MedPharmics, LLC**Subject No:** 11161160**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:58[Back to Form](#)**1. Data Origin**

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------|---------------|
| Mar-08-2021 09:29:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: SITE | Initial Entry |

2. Sample Type

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|----------------------------------|---------------|
| Mar-08-2021 09:29:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: NASAL_SWAB | Initial Entry |

3. Sample Collected?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------------|--|---|
| Mar-08-2021 10:41:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Deleted | Close Auto Query |
| Mar-08-2021 09:29:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto query (autoquery) | Query 1: Candidate | 'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate. |
| Mar-08-2021 09:29:58 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES Date of Collection: Mar/1/2021 | Initial Entry |

5.a

| Date | Location | User | Value | Reason |
|---|-----------------|------------------|---|---------------|
| Mar-08-2021 10:41:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJ05X | Initial Entry |

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

5.a Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-08-2021 10:41:09 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRJ05X | Initial Entry |

5.b

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-08-2021 10:41:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Sample ID: BRJ05Y | Initial Entry |

5.b Sample ID

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|------------------------------|---------------|
| Mar-08-2021 10:41:25 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: BRJ05Y | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Was there a temporary delay of vaccination?

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: NO | Initial Entry |

2. Treatment Name

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: BNT162b2 | Initial Entry |

3. Formulation:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|---------------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INJECTION | Initial Entry |

4. Dose Date Time:

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Mar/1/2021 09:32 | Initial Entry |

5. Anatomical Location:

| Date | Location | User | Value | Reason |
|---|-----------------|-------------------------|--------------------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: DELTOID MUSCLE | Initial Entry |

6. Body Side:

| Date | Location | User | Value | Reason |
|----------------------|-----------------|------------------|--------------------|---------------|
| Mar-08-2021 09:30:38 | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|--|--|---------------------|------|--|
| (UTC-06:00) Central Time (US & Canada) | | (b) (4), (b) (6) | LEFT | |
|--|--|---------------------|------|--|

7. Route:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|-------------------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: INTRAMUSCULAR | Initial Entry |

8. Actual Dose:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30.0 | Initial Entry |

9. Unit:

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|--------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ug | Initial Entry |

10. Timeframe Subject Was Observed

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|----------------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: 30 MINUTES | Initial Entry |

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

| Date | Location | User | Value | Reason |
|--|-----------------|---------------------|---------------------------|---------------|
| Mar-08-2021 09:30:38 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: YES | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

1. Subject Status

| Date | Location | User | Value | Reason |
|--|-----------------|-------------------------|---|---------------|
| Oct-30-2020 11:27:14 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: FOLLOW-UP | Initial Entry |
| Sep-09-2020 10:32:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: ENROLLED/RANDOMIZED | Initial Entry |
| Sep-09-2020 10:31:10 (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 |
|--|-----------------|---------------------|--------------------|---|
| Jan-27-2021 01:29:33 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Closed | Response satisfies query |
| Jan-25-2021 16:58:31 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Answered | COVID ILLNESS VISIT 13JAN2021 |
| Jan-21-2021 13:56:19 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Query 1: Opened | Illness eDiary: Subject reported "Yes" for the question "Have you experienced any of the following?" for the COVID-19 symptoms or diagnosis on 11JAN2021. But there is no COVID Illness visit reported in the database. Please clarify. |
| Oct-30-2020 11:27:14 | ACV0PFEINFP6000 | auto calc | Data Entry: | Initial Entry |

090177e196ae3f2e\Final\Final On: 01-Apr-2021 05:11 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1116

Subject No: 11161160

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1116) MedPharmics, LLC

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:58

| | | | | |
|---|-----------------|----------------------|----------------------------------|---------------|
| (UTC-06:00) Central Time (US & Canada) | | (autocalc) | Oct/26/2020 | |
| Sep-09-2020 10:32:34 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | auto calc (autocalc) | Data Entry: Sep/9/2020 | Initial Entry |
| Sep-09-2020 10:31:10 (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, Signed, Verified

Site No: 1116

Site Name: (1116) MedPharmics, LLC

Subject No: 11161160

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:58

[Back to Form](#)

I. Casebook Signature

| Date | Location | User | Value | Reason |
|---|-----------------|---------------------|--|---------------|
| Nov-05-2020 16:26:45 (UTC-06:00) Central Time (US & Canada) | ACV0PFEINFP6000 | (b) (4), (b) (6) | Data Entry: Click Here to Enable | Initial Entry |