

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** COHORT\_SELECTION

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

<b>Header Text:</b> c4591001	<b>Form:</b> MAIN INFORMED CONSENT
<b>Visit:</b> COHORT_SELECTION	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Informed Consent		
1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/18/2020

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001  
**Visit:** COHORT\_SELECTION **Form:** DEMOGRAPHY  
**Form Version:** 15-Sep-2020 21:54 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1030 **Site Name:** (1030) University Hospital of Cleveland  
**Subject No:** 10301110 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Demography		
1.	Subject ID	[10301110]
2.	Birth Date:	(b) (6) 1970
3.	Sex:	FEMALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

<b>Header Text:</b> c4591001	<b>Form:</b> DATE OF VISIT
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Sep/18/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 15-Sep-2020 21:52  
**Site No:** 1030  
**Subject No:** 10301110  
**Generated By:** (b) (4)

**Form:** DISPOSITION - SCREENING  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1030) University Hospital of Cleveland  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Disposition - Screening		
1.	Date of Completion/Discontinuation /Death	Sep/18/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**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 _____

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:56

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/18/2020
2.	Weight:	[58.0]
3.	Unit:	kg
4.	Height:	[162.56]
5.	Unit:	cm
6.	Body Mass Index:	[21.9]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.7]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Sep/18/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** RANDOMIZATION

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/18/2020
2.	Randomization Number:	[92835]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP16L8]
5.b	Sample ID	[BPHPNL]
5.c	Sample ID	[BPHPNM]

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

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

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BP16L7]
-----	-----------	----------

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** VACCINATION

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/18/2020 13:40
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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> REACTOGENICITY DIARY
<b>Visit:</b> V1_DAY1_VAX1_L	<b>Form Status:</b> Data Complete, Locked, Frozen, Verified
<b>Form Version:</b> 06-Jul-2020 21:53	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Oct/9/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Oct/9/2020
----	-------	------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[98.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Oct/9/2020
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1030

**Subject No:** 10301110

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

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

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Oct/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	[BR2N81]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** VACCINATION

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Oct/9/2020 09:05
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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/6/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/6/2020
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	[BP1676]
5.b	Sample ID	[BSHZC3]
5.c	Sample ID	[BSHZC4]

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/7/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Jan/7/2021
2.	Date of First Symptom Started:	Jan/6/2021
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Jan/12/2021

**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?	NO
4.f	Symptoms:	NEW LOSS OF TASTE OR SMELL
	Was symptom present?	YES
4.g	Symptoms:	NEW OR INCREASED SORE THROAT
	Was symptom present?	YES
4.h	Symptoms:	DIARRHEA
	Was symptom present?	NO
4.i	Symptoms:	VOMITING
	Was symptom present?	NO

**Symptoms - Other**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)





**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** MICROBIOLOGY SPECIMEN

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Jan/7/2021
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]

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Jan/7/2021
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	[RW84460]
-----	-----------	-----------

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[A SELF SWAP WAS DONE]

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021**Form:** HEALTH CARE UTILIZATION**Form Version:** 10-Dec-2020 02:26**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Health Care Utilization**

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

**Health Care Utilization Other**

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

**Health Care Utilization**

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

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 **Form:** RESPIRATORY TREATMENT  
**Form Version:** 06-Jul-2020 21:53  
**Site No:** 1030 **Site Name:** (1030) University Hospital of Cleveland  
**Subject No:** 10301110 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** RESPIRATORY TREATMENT

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Respiratory Treatment**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [COVID-19]  Date of Diagnosis: Jan/7/2021
3.	Toxicity Grade:	1

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Illness Details**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Lab Chemistry Details**

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

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	C Reactive Protein_PX329	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

5.b	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Alanine Aminotransferase_PX30	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Aspartate Aminotransferase_PX28	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Alkaline Phosphatase_PX35	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Bilirubin_PX21	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

5.f	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Blood Urea Nitrogen_PX47	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	
5.g	Sponsor ID:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Test:	Creatinine_PX48	
	Result:	Not Applicable _____	<a href="#">Comments</a>
		[ ]	
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____	<a href="#">Comments</a>
		Low [ ] High [ ] Unit	

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Laboratory Data Hematology**

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

**Lab Result**

5.a	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

5.b	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Hematocrit_PX2	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.c	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Erythrocytes_PX3	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

5.d	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Platelets_PX5	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.e	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Leukocytes_PX7	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

5.f	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Neutrophils_PX608	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.g	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Eosinophils_PX609	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

5.h	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Monocytes_PX612	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>
5.i	Sponsor ID:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Test:	Basophils_PX610	
	Result:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	Not Done:	Not Applicable _____ [ ]	<a href="#">Comments</a>
	LNMT	Not Applicable _____ Low [ ] High [ ] Unit	<a href="#">Comments</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Oxygenation Parameters**

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

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS  
**Form Version:** 06-Jul-2020 21:55  
**Site No:** 1030 **Site Name:** (1030) University Hospital of Cleveland  
**Subject No:** 10301110 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

#	Sponsor-Defined Identifier	Category for Medication	Concomitant Medications Pre-specified	Name of Medication	Start Date	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Concomitant Medications**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

<b>Header Text:</b> c4591001					
<b>Visit:</b> POT_COVID_ILL 1			<b>Form:</b> IMAGING		
<b>Form Version:</b> 06-Jul-2020 21:53					
<b>Site No:</b> 1030			<b>Site Name:</b> (1030) University Hospital of Cleveland		
<b>Subject No:</b> 10301110			<b>Subject Initials:</b> ---		
<b>Generated By:</b> (b) (4)			<b>Generated Time (GMT):</b> 29-Mar-2021 04:44		
#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** IMAGING

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

[Form Comments](#)

[eCRF Audit Trail History](#)

**Imaging**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS CONVALESCENT  
Feb/12/2021

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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



**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY  
Feb/12/2021

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject's convalescent visit overlapped with her vaccination 3 visits]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BR8V06]
5.b	Sample ID	[BS7D5V]
5.c	Sample ID	[BS7D5W]

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**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:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**COVID-19 Repeat Swab**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_REPEAT\_SWAB - New  
Unscheduled Visit

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

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

**Form Status:** Not Started

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> c4591001		<b>Form:</b> UNPLANNED VISIT
<b>Visit:</b> Unplanned - New Unscheduled Visit		<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:04		<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030		<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110		<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)		
<b>Unplanned Assessments</b>		
1.	Assessments	

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	pharyngitis streptococcal	Jan/17/2021 UNK:UNK	NO End Date Time: Jan/30/2021 UNK:UNK	<a href="#">Repeating Pages</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

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

**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[pharyngitis streptococcal]
4.	Start Date Time:	Jan/17/2021 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Jan/30/2021 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [Bacterial Infection]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Answered Queries

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2021086858]



**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[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	[ ]

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

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

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[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:	//

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[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?	

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[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?	



<b>Header Text:</b> c4591001			
<b>Visit:</b> Logs		<b>Form:</b> TRANSFUSIONS	
<b>Form Version:</b> 22-Apr-2020 21:03			
<b>Site No:</b> 1030		<b>Site Name:</b> (1030) University Hospital of Cleveland	
<b>Subject No:</b> 10301110		<b>Subject Initials:</b> ---	
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 04:44	
#	Transfusion Type	Date of Transfusion	Form Instance
1.			<a href="#">Repeating Pages</a>

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

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

**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:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Nov/6/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001  
**Visit:** Unplanned Vaccination - Unscheduled      **Form:** VITAL SIGNS - TEMP  
**Form Version:** 20-Feb-2021 02:16      **Form Status:** Not Started  
**Site No:** 1030      **Site Name:** (1030) University Hospital of Cleveland  
**Subject No:** 10301110      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 04:44

**Vital Signs**

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

**Vital Signs Details**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** LAB URINALYSIS - PREGNANCY TEST

**Form Version:** 20-Feb-2021 02:14

**Form Status:** Not Started

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Lab Urinalysis**

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

**Lab Result**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**Vaccination**

1.	Was there a temporary delay of vaccination?	
2.	Treatment Name	[ ]
3.	Formulation:	
4.	Dose Date Time:	//
5.	Anatomical Location:	
6.	Body Side:	
7.	Route:	
8.	Actual Dose:	[ ]
9.	Unit:	
10.	Timeframe Subject Was Observed	
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME - MONTH 1
<b>Visit:</b> Unplanned Vaccination - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 10-Oct-2020 15:57	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

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



<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME - MONTH 6
<b>Visit:</b> Unplanned Vaccination - Unscheduled	<b>Form Status:</b> Not Started
<b>Form Version:</b> 10-Oct-2020 16:01	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

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

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Disposition - Follow-Up**

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

**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:** 1030      **Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Dec/17/2020
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled

**Form:** FURTHER VACCINATION CONFIRMATION

**Form Version:** 10-Dec-2020 02:25

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Further Vaccination Confirmation**

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per 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:** 1030

**Subject No:** 10301110

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Dec/18/2020
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

<b>Header Text:</b> c4591001		<b>Form:</b> WITHDRAWAL OF CONSENT
<b>Visit:</b> Disposition - Unscheduled		<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:03		<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030		<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110		<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)		
<b>Withdrawal Of Consent</b>		
1.	Withdrawal of Consent Date :	//

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DEATH DETAILS CODED

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Death Details**

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

**Cause of Death**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Feb/12/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** INFORMED CONSENT - FURTHER VACCINATION

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Informed Consent - Further Vaccination**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/12/2021
----	--------------	--

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1030

**Subject No:** 10301110

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

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

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Form Comments**

**Inclusion Criteria Not Met**

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

**Exclusion Criteria Met**

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

<b>Header Text:</b> c4591001	<b>Form:</b> DISPOSITION - SCREENING FOR FURTHER VACCINATION
<b>Visit:</b> V101_VAX3	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Form Version:</b> 10-Dec-2020 02:31	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

[eCRF Audit Trail History](#)

**Disposition - Screening for Further Vaccination**

1.	Date of Completion/Discontinuation /Death :	Feb/12/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Lab Urinalysis**

1.	Lab Panel:	URINALYSIS
2.	Lab Sub-Panel:	PREGNANCY
3.	Collection Date:	Feb/12/2021
4.	Laboratory Name and Address (Derived)	[STUDY SITE]
5.	Specimen Type:	URINE

**Lab Result**

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

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[subject's convalescent visit overlapped with her vaccination 3 visits]

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[ ]
5.b	Sample ID	[ ]
5.c	Sample ID	[ ]

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1030

**Subject No:** 10301110

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

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

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/12/2021
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	[BR8V0D]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** VACCINATION

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/12/2021 13:55
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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

<b>Header Text:</b> c4591001	
<b>Visit:</b> V102_VAX4	<b>Form:</b> DATE OF VISIT
<b>Form Version:</b> 22-Apr-2020 21:02	<b>Form Status:</b> Data Complete, Frozen, Verified
<b>Site No:</b> 1030	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Subject No:</b> 10301110	<b>Subject Initials:</b> ---
<b>Generated By:</b> (b) (4)	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Mar/4/2021
2.	Erroneous Visit	



**Header Text:** c4591001

**Visit:** V102\_VAX4

**Form Version:** 14-Jan-2021 02:21

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** LAB URINALYSIS - PREGNANCY TEST

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Lab Urinalysis**

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

**Lab Result**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1030

**Subject No:** 10301110

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

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

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Mar/4/2021
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	[BR8V10]
-----	-----------	----------

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** VACCINATION

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/4/2021 09:20
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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V103\_MONTH1

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME
<b>Visit:</b> V103_MONTH1	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

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:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME
<b>Visit:</b> V104_MONTH6	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

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:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	



<b>Header Text:</b> c4591001	<b>Form:</b> CONTACT OUTCOME
<b>Visit:</b> V105_MONTH18	<b>Form Status:</b> Not Started
<b>Form Version:</b> 22-Apr-2020 21:04	<b>Site Name:</b> (1030) University Hospital of Cleveland
<b>Site No:</b> 1030	<b>Subject Initials:</b> ---
<b>Subject No:</b> 10301110	<b>Generated Time (GMT):</b> 29-Mar-2021 04:44
<b>Generated By:</b> (b) (4)	

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

**Form:** DISPOSITION - TREATMENT

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

**Form Status:** Not Started

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

**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:** 1030

**Subject No:** 10301110

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

**Form:** SUBJECT STATUS

**Form Status:** Data Complete, Verified

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/6/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** CASEBOOK SIGNATURE FORM

**Form Status:** Data Complete, Verified

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

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

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-18-2020 13:02:50 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-18-2020 13:04:39 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2	Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4	Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5	Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** RESPIRATORY TREATMENT - Comments

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
6	Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2	Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** ILLNESS DETAILS - SEVERE - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4	Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.b	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.b	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.b	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.b	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.c	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.c	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.c	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.c	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.d	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.d	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.d	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.d	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.e	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.e	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.e	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.e	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 f	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 f	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 f	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 f	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.g	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.g	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.g	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.g	Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.a	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.b	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.b	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.b	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.b	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.c	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.c	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.c	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.c	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.d	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.d	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.d	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.d	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.e	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.e	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.e	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.e	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 f	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 f	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 f	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 f	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.g	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.g	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.g	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.g	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 h	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 h	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 h	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5 h	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.i	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.i	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.i	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.i	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.j	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.j	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.j	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

**Form Version:** 15-Sep-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5.j	Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** VITAL SIGNS - COVID - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-07-2021 17:01:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-07-2021 17:01:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2.a	Jan-07-2021 17:01:48 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** OXYGENATION PARAMETERS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-07-2021 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** OXYGENATION PARAMETERS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-07-2021 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** OXYGENATION PARAMETERS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2	Jan-07-2021 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) ( )	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** OXYGENATION PARAMETERS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Jan-07-2021 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2	Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4	Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
5	Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
6	Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
1	Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
2	Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
3	Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** IMAGING - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
4	Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** V101\_VAX3

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

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Item	Date	User	Comment
Form	Feb-12-2021 19:39:40 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

**Form Status:** Data Complete, Verified

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

Robert Salata	Approved	Jan-26-2021 12:52:01 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, RobertSalata, 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-07-2021 16:49:14 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
---------	-----	---	--	-----------------------------------

**Affidavit:**

N/A

Robert Salata	Approved	Nov-13-2020 16:04:26 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
---------------	----------	---	------	--------

**Affidavit:**

By my dated signature below, I, RobertSalata, 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.

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** COHORT\_SELECTION - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Sep-18-2020 13:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:01:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

**I. Consent Was:**

Date	Location	User	Value	Reason
Sep-18-2020 13:01:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/18/2020	Initial Entry

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Subject ID**

Date	Location	User	Value	Reason
Sep-18-2020 13:00:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10301110	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:00:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6)/1970	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-18-2020 13:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEMALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
Sep-18-2020 13:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-18-2020 13:01:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*I. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-18-2020 13:02:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:52

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-18-2020 13:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-18-2020 13:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-18-2020 13:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 58.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 162.56	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-18-2020 13:07:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21.9	Initial Entry
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

**7.a**

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 15-Sep-2020 21:56

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 97.7 <b>Temperature Unit:</b> F <b>Temperature Location</b> ORAL CAVIT <b>::</b> Y	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.7	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-18-2020 13:07:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 15-Sep-2020 21:51**Site No:** 1030**Subject No:** 10301110**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1030) University Hospital of Cleveland**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

**Header Text:** c4591001

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

**Form Version:** 15-Sep-2020 21:51

**Site No:** 1030

**Subject No:** 10301110

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

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

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**6.a Sponsor ID:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 113	Initial Entry

**6.a Test:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Choriogonadotropin Beta_PX113	Initial Entry

**6.a Result:**

Date	Location	User	Value	Reason
Sep-18-2020 13:08:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-18-2020 19:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-18-2020 19:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 92835	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:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-18-2020 13:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-18-2020 13:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-18-2020 19:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-18-2020 13:37:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 13:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 13:29:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-18-2020 19:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP16L8	Initial Entry

**5.a Sample ID**

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: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-18-2020 19:46:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP16L8	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-18-2020 19:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPHPNL	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-18-2020 19:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPHPNL	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-18-2020 19:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPHPNM	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-18-2020 19:47:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPHPNM	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-18-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Sep-18-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-18-2020 19:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-18-2020 13:37:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-18-2020 13:30:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/18/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-18-2020 19:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP16L7	Initial Entry

**5.a Sample ID**

**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:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Sep-18-2020 19:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP16L7	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-18-2020 19:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-18-2020 19:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-18-2020 19:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Sep-18-2020 19:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/18/2020 13:40	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-18-2020 19:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-18-2020 19:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-18-2020 19:58:04	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-18-2020 19:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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-18-2020 19:58:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-18-2020 13:09:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*1. Date of Visit*

Date	Location	User	Value	Reason
Oct-09-2020 18:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:54

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Oct-09-2020 18:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-09-2020 18:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Temperature:</b> 98.5 <b>Temperature Unit:</b> F <b>Temperature Location</b> ORAL CAVIT <b>::</b> Y	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Oct-09-2020 18:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Temperature:**

Date	Location	User	Value	Reason
Oct-09-2020 18:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Oct-09-2020 18:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> F	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Oct-09-2020 18:14:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 15-Sep-2020 21:51**Site No:** 1030**Subject No:** 10301110**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1030) University Hospital of Cleveland**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 15-Sep-2020 21:51

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

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

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

6.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Oct-09-2020 18:15:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEGATIVE	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (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:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-09-2020 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Oct-09-2020 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Oct-12-2020 09:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-10-2020 05:15:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-09-2020 18:15:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-12-2020 09:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR2N81	Initial Entry

**5.a Sample ID**

**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:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Oct-12-2020 09:04:54 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR2N81	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Oct-09-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Oct-09-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Oct-09-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Oct-09-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020 09:05	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Oct-09-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Oct-09-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Oct-09-2020 18:13:30	ACV0PFEINFP6000	auto calc	<b>Data Entry:</b>	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

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

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Oct-09-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 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
Oct-09-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Nov-06-2020 11:45:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/6/2020	Initial Entry

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Nov-06-2020 11:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-06-2020 11:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-06-2020 19:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-06-2020 11:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-06-2020 11:45:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Nov/6/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Nov-06-2020 19:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP1676	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Nov-06-2020 19:16:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP1676	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: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.b

Date	Location	User	Value	Reason
Nov-06-2020 19:16:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BSHZC3</b>	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 19:16:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHZC3	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-06-2020 19:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID: BSHZC4</b>	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-06-2020 19:16:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BSHZC4	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**I. Date of Visit**

Date	Location	User	Value	Reason
Feb-18-2021 14:39:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Closed	Response satisfies query
Feb-17-2021 00:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Closed, CONVA visit added
Feb-16-2021 22:08:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Changed data per query
Feb-15-2021 21:17:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Completed
Feb-12-2021 05:08:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: 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.
Feb-09-2021 08:46:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Reissued:Opened	Clin: Please keep query open until resolution
Feb-09-2021 07:19:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	still waiting on information, will update when it comes in
Feb-02-2021 14:33:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 4: Reissued:Opened	Clin: Please keep query open until resolution
Feb-01-2021 18:46:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	waiting for information
Feb-01-2021 10:48:01 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Salim Bouguermouh	Query 4: Opened	Clin: It was stated in the SAE report

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)		(b) (4)		#2021086858 that the subject was hospitalized. Please obtain subject medical records and update as appropriate the CRF forms (COVID TEST, ILL SEVERE, LAB CHEM/HME, VITAL COV, PULSE OX, OXYGEN, VASOPRESS, IMAGING)
Jan-19-2021 03:51:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Data updated
Jan-12-2021 00:13:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Candidate	Please review this query once data is entered on ILL POTEN form.
Jan-08-2021 14:16:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	waiting on more information about the visit from coordinators to complete case report forms. thanks
Jan-08-2021 07:41:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly review and complete 'Illness Details form' at this visit. Thank you.
Jan-07-2021 16:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Jan-07-2021 16:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Jan-07-2021 16:49:13 (UTC-05:00) Eastern 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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

				missing. Please review and update as appropriate.
Jan-07-2021 16:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Jan-07-2021 16:49:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021**Form Version:** 10-Dec-2020 02:29**Site No:** 1030**Subject No:** 10301110**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit  
Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1030) University Hospital of Cleveland**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-18-2021 14:35:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-16-2021 21:51:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Feb-15-2021 22:19:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: Please Date of Assessment 7Jan2021 cannot be before the symptoms start date 17Jan2021
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Feb-17-2021 10:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 21:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-16-2021 21:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Transcription Error
Feb-16-2021 20:46:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Data is discrepant. Per source, symptoms started on 06-Jan-2021. Please review and reconcile.
Feb-15-2021 21:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/17/2021	Transcription Error
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/6/2021	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form Version: 10-Dec-2020 02:29

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 14:36:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-17-2021 11:12:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-17-2021 11:12:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-16-2021 21:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Feb-16-2021 21:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-16-2021 21:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-16-2021 21:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved:  Jan/12/2021	Transcription Error
Feb-16-2021 20:48:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Please review source and consider adding other symptom of "fatigue".
Feb-16-2021 20:47:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Data is discrepant. Please add new information clarifying stop date, as noted in source on 12-Jan-2021.
Feb-09-2021 08:44:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please keep query open until resolution
Feb-09-2021 07:18:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	still waiting on information, will update when it comes in
Feb-02-2021 14:34:18 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Salim Bouguermouh	Query 1: Reissued:Opened	Clin: Please keep query open until resolution

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021**Form Version:** 10-Dec-2020 02:29**Site No:** 1030**Subject No:** 10301110**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit  
Trail History**Form Status:** Data Complete, Frozen, Not Complete**Site Name:** (1030) University Hospital of Cleveland**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44

(US & Canada)		(b) (4)		
Feb-01-2021 18:47:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	waiting for this information
Feb-01-2021 10:51:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021086858 that the subject experienced STREP THROAT on 19Jan2021. Please confirm that at least one symptom was ongoing at the time the STREP THROAT was diagnosed
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEVER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**4.a Was symptom present?**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.b**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED COUGH	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form Version: 10-Dec-2020 02:29

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Not Complete

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			Symptom Pre sent: YES	
--	--	--	-----------------------	--

4.b Symptoms:

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW OR INCREASED SH : ORTNESS OF BREATH <b>Symptom Present:</b> NO	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTNESS O F BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.d

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: CHILLS <b>Symptom Present:</b> YES	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.d Symptoms:

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.e

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED MUSCLE PAIN <b>Symptom Present:</b> NO	Initial Entry

4.e Symptoms:

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW LOSS OF TASTE OR SMELL <b>Symptom Present:</b> YES	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

4.f Symptoms:

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.g

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> NEW OR INCREASED SORE THROAT <b>Symptom Present:</b> YES	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE THROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

4.h

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> DIARRHEA <b>Symptom Present:</b> NO	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

Form Version: 10-Dec-2020 02:29

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

**4.h Symptoms:**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**4.h Was symptom present?**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> VOMITING <b>Symptom Present:</b> NO	Initial Entry

**4.i Symptoms:**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**4.i Was symptom present?**

Date	Location	User	Value	Reason
Jan-07-2021 16:53:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Date	Location	User	Value	Reason
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/7/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATERIAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NASOPHARYNX	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDROME C ORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Jan-13-2021 16:21:42	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		query
Jan-12-2021 21:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Jan-12-2021 21:54:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> POSITIVE	New Information
Jan-12-2021 00:57:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please update incomplete item. Thank you.

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Jan-12-2021 21:54:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> AWAITING RESULTS	Initial Entry

9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Jan-12-2021 00:57:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-11-2021 16:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Jan-11-2021 16:36:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NALT UNKNOWN	Transcription Error
Jan-11-2021 02:22:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	As per CRF CR Section 8.31.7, If the Trade Name is not known, please enter NALT Unknown

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

				in the specified field, Thank you. (b) (4)
Jan-07-2021 16:55:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NAULT UNKNO WN	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-07-2021 16:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-07-2021 16:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB_SELF	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-16-2021 21:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Feb-15-2021 21:27:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Date of Collection is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Jan-07-2021 16:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-07-2021 16:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Jan-07-2021 16:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Jan/7/2021	Initial Entry

**5.a**

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

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

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Jan-07-2021 16:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> RW84460	Initial Entry
---	-----------------	---------------------	---	---------------

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-07-2021 16:56:25 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RW84460	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Jan-07-2021 16:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-07-2021 16:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Jan-07-2021 16:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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-07-2021 16:56:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> A SELF SWAP WAS DONE	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

*I.a*

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> SPECIALIST <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

*I.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

*I.a Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.b*

Date	Location	User	Value	Reason
Feb-19-2021 20:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	New Information
Feb-17-2021 21:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Initial Entry
Feb-17-2021 21:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b>	Transcription Error

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> EMERGENCY ROOM <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry
---	-----------------	---------------------	---	---------------

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROOM	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Feb-22-2021 10:20:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-19-2021 20:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-19-2021 20:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Feb-19-2021 19:58:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Data is discrepant. Please remove and consider updated to "no", as this particular visit only coincides with the covid illness visit performed on 07-Jan-2021.
Feb-18-2021 14:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-17-2021 21:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits or Contacts:</i>  1	Initial Entry
Feb-17-2021 21:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-17-2021 21:47:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-09-2021 08:45:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please keep query open until resolution

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021 **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History  
**Form Version:** 10-Dec-2020 02:26 **Form Status:** Data Complete, Frozen, Not Complete  
**Site No:** 1030 **Site Name:** (1030) University Hospital of Cleveland  
**Subject No:** 10301110 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

Feb-09-2021 07:19:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	still waiting on information, will update when it comes in
Feb-02-2021 14:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please keep query open until resolution
Feb-01-2021 18:48:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	waiting for this information
Feb-01-2021 10:46:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021086858 that the subject presented to emergency room for sore throat that was not getting better. Please review and update as appropriate this SOD CRF page
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**I.c**

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> PRIMARY CARE PHYSICIAN <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

**I.c Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE PHYSICIAN	Initial Entry

**I.c Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

I.d

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> URGENT CARE <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

I.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

I.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

I.e

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> TELEPHONE CONSULTATION <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

I.f

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Feb-19-2021 20:10:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH R <b>Occurrence of Visits or Contacts:</b> NO	New Information
Feb-17-2021 21:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTHER <b>Occurrence of Visits or Contacts:</b> YES <i>Number of Visits or Contacts:</i> 1	Transcription Error
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OTH R <b>Occurrence of Visits or Contacts:</b> NO	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

*If Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

*If Occurrence of Visits or Contacts:*

Date	Location	User	Value	Reason
Feb-23-2021 04:13:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_HOHC002_03
Feb-22-2021 10:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-20-2021 20:33:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW7331091;"Other Type of Practitioner Specify" is not null, but Occurrence of Visits or Contacts for "Other" is NO. Please review and update as appropriate.
Feb-19-2021 20:10:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-19-2021 20:10:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Feb-19-2021 20:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Please remove as this data should only be recorded for the COVID illness visit dated 07-Jan-2021.
Feb-17-2021 21:48:06 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

& Canada)				
Feb-17-2021 21:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	"Other" is selected , however other specific item is blank. Please review and update as appropriate.
Feb-17-2021 21:47:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Number of Visits or Contacts: 1	Transcription Error
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Feb-25-2021 08:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-23-2021 17:18:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-22-2021 20:39:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Feb-22-2021 20:39:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-22-2021 10:29:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Please remove this data as only data from covid illness visit dated 07-Jan-2021 should be captured.
Feb-19-2021 19:57:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	per coordinators, subject was under observation.
Feb-19-2021 13:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please clarify 'observation' in terms of Other Type of Practitioner?

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Not Complete

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Feb-17-2021 21:48:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> observation	Initial Entry
---	-----------------	---------------------	-----------------------------------	---------------

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

Date	Location	User	Value	Reason
Feb-18-2021 14:38:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Feb-17-2021 21:50:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	subject was hospitalized d/t strep throat not because of a covid-19 illness
Feb-09-2021 08:45:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Clin: Please keep query open until resolution
Feb-09-2021 07:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	still waiting on information, will update when it comes in
Feb-02-2021 14:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued:Opened	Clin: Please keep query open until resolution
Feb-01-2021 18:48:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	waiting for this information
Feb-01-2021 10:55:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: It was stated in the SAE report #2021030811 that the subject was hospitalized on 19 Jan2021 for STREP THROAT. Please review and update as appropriate potential COVID-19 illness visit CRF forms
Feb-01-2021 10:55:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-01-2021 10:54:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021030811 that in De2020 the subject was hospitalized on

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen, Not Complete

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

				19Jan2021 for STREP THROAT. Please review and update as appropriate potential COVID-19 illness visit CRF forms
Jan-07-2021 16:57:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: RESPIRATORY TREATMENT - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Concomitant Non-drug Treatment Pre-specified:**

Date	Location	User	Value	Reason
Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Treatment:**

Date	Location	User	Value	Reason
Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Treatment:**

Date	Location	User	Value	Reason
Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Jan-07-2021 16:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Jan-12-2021 21:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> POTENTIAL COVID-19 ILLNESS	Initial Entry

**2. Was a diagnosis obtained for Potential COVID-19 Illness?**

Date	Location	User	Value	Reason
Feb-22-2021 09:41:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-22-2021 09:17:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-19-2021 13:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	New Information
Feb-19-2021 13:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-19-2021 13:39:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID-19  Date of Diagnosis:  Jan/7/2021	New Information
Feb-18-2021 17:10:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Data is discrepant from source. Please review covid illness visit dated 07-Jan-2021 and ensure correct visit data is being captured.
Feb-18-2021 14:37:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Closed	Response satisfies query
Feb-18-2021 10:38:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	CLINQUERY: Since local SARS-CoV-2-NAAT test was

<b>Header Text:</b> c4591001 <b>Visit:</b> POT_COVID_ILL 1 - Unscheduled Visit on Jan/07/2021 <b>Form:</b> ILLNESS DETAILS - eCRF Audit Trail History <b>Form Version:</b> 06-Jul-2020 21:52 <b>Form Status:</b> Data Complete, Frozen <b>Site No:</b> 1030 <b>Site Name:</b> (1030) University Hospital of Cleveland <b>Subject No:</b> 10301110 <b>Subject Initials:</b> --- <b>Generated By:</b> (b) (4) <b>Generated Time (GMT):</b> 29-Mar-2021 04:44				
				positive on 07Jan2021, please consider updating the date of the COVID-19 diagnosis as 07Jan2021.
Feb-16-2021 22:04:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID-19  Date of Diagnosis:  Jan/19/2021	New Information
Feb-16-2021 21:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-16-2021 21:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  Strep Throat  Date of Diagnosis:  Jan/19/2021	New Information
Feb-15-2021 22:16:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: It was stated in the SAE report AER# 2021086858 that the subject was hospitalized on 19Jan2021 for STREP THROAT. Please review and consider updating the SAE report by adding also the SAE term COVID-19 ILLNESS
Feb-15-2021 21:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-15-2021 21:19:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Transcription Error
Feb-09-2021 08:45:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued:Opened	Clin: Please keep query open until resolution

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: ILLNESS DETAILS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Feb-09-2021 07:17:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	still waiting on info- will update
Feb-02-2021 14:34:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Reissued: Opened	Clin: Please keep query open until resolution
Feb-01-2021 18:48:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	waiting for this information
Feb-01-2021 10:58:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 1: Opened	Clin: It was stated in the SAE report #2021030811 that the subject was hospitalized on 19Jan2021 for STREP THROAT. Please review and consider updating the SAE report by adding also the SAE term COVID-19 ILLNESS
Jan-12-2021 21:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Respiratory Illness Diagnosis:</i>  COVID 19  Date of Diagnosis:  Jan/7/2021	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-12-2021 21:55:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Jan-12-2021 21:55:46 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:51

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable Lab Normal Range: Not Applicable	Initial Entry

**5.a Sponsor ID:**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
---	-----------------	---------------------	--------------------------------------	---------------

5.a Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test:::</b> Not Applicable <b>Result:::</b> Not Applicable <b>Not Done:::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021  
**Form Version:** 15-Sep-2020 21:51  
**Site No:** 1030  
**Subject No:** 10301110  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF  
**Audit Trail History**  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1030) University Hospital of Cleveland  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			<b>Lab Normal Range:</b>	Not Applicable
--	--	--	--------------------------	----------------

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			<b>Result::</b>	Not Applicable
			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifi</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form Version: 15-Sep-2020 21:51

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			er:	le
			Test::	Not Applicab le
			Result::	Not Applicab le
			Not Done::	Not Applicab le
			Lab Normal Range:	Not Applicab le

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Initial Entry Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable
---	-----------------	---------------------	---	---

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:36 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021  
**Form Version:** 15-Sep-2020 21:55  
**Site No:** 1030  
**Subject No:** 10301110  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1030) University Hospital of Cleveland  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

**5.a Sponsor ID:**

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

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
---	-----------------	---------------------	--------------------------------------	---------------

5.a Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test:::</b> Not Applicable <b>Result:::</b> Not Applicable <b>Not Done:::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			<b>Lab Normal Range:</b>	Not Applicable
--	--	--	--------------------------	----------------

5.c Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			<b>Result::</b>	Not Applicable
			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.d Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifi</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			er:	le	
			Test::	Not Applicab le	
			Result::	Not Applicab le	
			Not Done::	Not Applicab le	
			Lab Normal Range:	Not Applicab le	

5.e Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Initial Entry Not Applicable Not Applicable Not Applicable Not Applicable Not Applicable
---	-----------------	---------------------	---	---

5.f Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

5.g Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

**5.h**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable <b>Not Done::</b> Not Applicable <b>Lab Normal Range:</b> Not Applicable	Initial Entry

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021  
**Form Version:** 15-Sep-2020 21:55  
**Site No:** 1030  
**Subject No:** 10301110  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1030) University Hospital of Cleveland  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Not Applicable Test:: Not Applicable Result:: Not Applicable Not Done:: Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form Version:** 15-Sep-2020 21:55

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

			<b>Lab Normal Range:</b>	Not Applicable	
--	--	--	--------------------------	----------------	--

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit  
Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Not Applicable <b>Test::</b> Not Applicable <b>Result::</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Jan/07/2021

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

			<b>Not Done::</b>	Not Applicable
			<b>Lab Normal Range:</b>	Not Applicable

5.j Sponsor ID:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j Not Done:

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Jan-07-2021 17:00:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:52**Form Status:** Data Complete, Frozen**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Appli cable <b>Systolic::</b> Not Appli cable <b>Diastolic::</b> Not Appli cable <b>Respiratory Rate in respira tions/minute:</b> Not Appli cable <b>Heart Rate in beats/minute:</b> Not Appli cable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
---	-----------------	---------------------	--------------------------------------	---------------

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Jan-07-2021 17:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

*1. Date:*

Date	Location	User	Value	Reason
Jan-07-2021 17:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

*2.a*

Date	Location	User	Value	Reason
Jan-07-2021 17:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Oxygen Saturation:</b> Not Applicable	Initial Entry

*2.a Record Identifier:*

Date	Location	User	Value	Reason
Jan-07-2021 17:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

*2.a SPO2 Pulse Oximetry %*

Date	Location	User	Value	Reason
Jan-07-2021 17:01:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: OXYGENATION PARAMETERS - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Jan-07-2021 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Arterial Blood Gases PaO2 (mmHg):**

Date	Location	User	Value	Reason
Jan-07-2021 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. FiO2 (Fraction of Inhaled Oxygen):**

Date	Location	User	Value	Reason
Jan-07-2021 17:02:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail  
History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Category:**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Concomitant Medications Pre-specified:**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Medication:**

*Provide the complete generic drug name (including salt form, where applicable). Where generic name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5. Start Date:**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on  
Jan/07/2021

Form: IMAGING - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Date of Assessment:**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Jan-12-2021 21:56:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail  
Feb/12/2021 History

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

**1. Date of Visit**

Date	Location	User	Value	Reason
Feb-15-2021 21:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/12/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Feb-15-2021 21:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Feb/12/2021 Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-15-2021 21:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-15-2021 21:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-19-2021 20:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Deleted	Close Auto Query
Feb-19-2021 20:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-19-2021 20:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/12/2021	Transcription Error
Feb-17-2021 10:27:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-16-2021 21:55:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query
Feb-16-2021 21:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled Visit on Feb/12/2021 **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Queries, Frozen, Verified**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

				review and update as appropriate.
Feb-16-2021 21:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Deleted	Close Auto Query
Feb-16-2021 21:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-16-2021 21:54:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Feb-16-2021 21:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-16-2021 20:44:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Per source, this subject's convalescent visit overlapped with her vaccination 3 visits. Please mark "no" and specify details accordingly. Please remove all barcodes from this page as they are recorded under Vax 3
Feb-15-2021 21:16:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 21:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-15-2021 21:15:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/12/2021	Initial Entry

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

Date	Location	User	Value	Reason
Feb-16-2021 21:55:50 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> subject's convalescent visit overlapped wi	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Feb/12/2021 Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

(US & Canada)	(b) (4), (b) (6)	th her vaccination 3 visits
---------------	------------------	-----------------------------

5.a

Date	Location	User	Value	Reason
Feb-19-2021 20:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR8V06	Initial Entry
Feb-16-2021 21:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	New Information
Feb-15-2021 21:16:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR8V0D	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Feb-19-2021 20:04:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8V06	Initial Entry
Feb-17-2021 03:49:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Feb-16-2021 21:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-16-2021 21:54:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Feb-16-2021 03:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7266538;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF  
Feb/12/2021 Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Feb-15-2021 21:16:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8V0D	Initial Entry
---	-----------------	------------------	------------------------------	---------------

5.b

Date	Location	User	Value	Reason
Feb-27-2021 10:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS7D5V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 05:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Mar-02-2021 15:03:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	DM: Do not issue query. Site to remove duplicate barcodes from V101. Query will be closed once completed.
Mar-02-2021 11:18:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Unfreeze visit 3 so i can update.
Mar-02-2021 05:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7565148; This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-27-2021 10:34:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS7D5V	Initial Entry

5.c

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled Visit on Feb/12/2021 Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Queries, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

Feb-27-2021 10:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS7D5W	Initial Entry
---	-----------------	---------------------	--	---------------

5.c Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 05:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Mar-02-2021 15:03:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Candidate	DM: Do not issue query. Site to remove duplicate barcodes from V101. Query will be closed once completed.
Mar-02-2021 11:19:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unfreeze v3 so i can update
Mar-02-2021 05:43:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7565149; This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-27-2021 10:35:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS7D5W	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Category:**

Date	Location	User	Value	Reason
Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Mar-08-2021 10:35:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Closed	Response satisfies query
Mar-05-2021 18:56:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Reissued: Opened	Clinical - Most recent SAE update (04Mar21) has NO information about COVID illness (ie original value in SAE is 'empty'). Please submit pertinent med Hx of recent COVID-19 illness (Jan 6-12 symptoms, per COVID Illness CRF pages)
Mar-05-2021 10:36:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Answered	Original value is correct
Mar-05-2021 10:35:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Opened	Clinical - please submit a SAE update with pertinent med Hx of recent COVID-19 illness (symptoms from Jan 6-12, 2021 per COVID Illness CRF pages)

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1030  
**Subject No:** 10301110  
**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Answered Queries  
**Site Name:** (1030) University Hospital of Cleveland  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 04:44

Mar-05-2021 10:32:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Mar-04-2021 13:50:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	SAE FOLLOW UP REPORT WAS SENT.
Mar-04-2021 07:51:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Reissued: Opened	Clinical Please submit the SAE closeout request ASAP to complete the changeover prior to date lock
Mar-03-2021 21:57:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> pharyngitis streptococcal	New Information
Mar-03-2021 05:37:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Closed	term updated in Inform
Mar-02-2021 11:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 7: Answered	New Information
Mar-02-2021 11:14:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> positive for Strep Throat	New Information
Mar-02-2021 02:41:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Opened	SAE RECON: AER#2021086858, the term was reported as 'positive for strep throat' in Safety database while recorded as 'Group A Streptococcal infection' in AE CRF. Please confirm correct term. If safety update is required, please submit

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				a follow-up form.
Mar-02-2021 00:26:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 6: Closed	Discrepancy has been closed.
Mar-01-2021 23:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Answered	Transcription Error
Mar-01-2021 23:05:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Group A Streptococ cal infection	Transcription Error
Mar-01-2021 06:40:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued: Opened	CODING: Term will not code as entered therefore Clarify GROUP A STREPTOCOCCAL as follows...The term is incomplete. Are you reporting INFECTION? TEST? TEST POSITIVE RESULT? Other? Please update the verbatim term to clarify. Thank you.
Feb-26-2021 11:32:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Per CRA that is the name i am to use for easy coding
Feb-26-2021 03:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFETMS Oracle (b) (4)	Query 6: Opened	Clarify GROUP A STREPTOCOCCAL as follows...The term is incomplete. Are you reporting INFECTION? TEST? TEST POSITIVE RESULT? Other? Please update the verbatim term to clarify. Thank you.
Feb-25-2021 19:41:48	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Group A Streptococ	New Information

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	cal	
Feb-25-2021 19:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	coordinators are aware.
Feb-25-2021 12:06:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	Clinical - for administrative purposes, please submit a SAE safety update stating that event 'Strep Throat' no longer meets serious criteria
Feb-22-2021 16:03:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Feb-18-2021 02:44:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	created in error is case is being FU directly with the site.
Feb-17-2021 06:35:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	GPDCLIN: Per protocol section 8.1., COVID-19 listed symptom SORE THROAT should have please triggered a potential COVID Illness Visit irrespective of perceived etiology or clinical significance . Please complete the potential COVID Illness CRF forms.
Feb-16-2021 22:15:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Feb-16-2021 14:55:47 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical Please submit a SAE update to report the past medical

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Eastern Time (US & Canada)				history of COVID illness, including symptom start and stop dates
Feb-15-2021 22:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Closed	Response satisfies query
Feb-15-2021 21:23:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	completed
Feb-10-2021 03:48:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	duplication of queries. new query already issued by efficacy team as resolution is pending additional information from site.
Feb-09-2021 08:46:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Reissued: Opened	Clin: Please keep query open until resolution
Feb-09-2021 07:18:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	still waiting on information, will update when it comes in
Feb-09-2021 07:17:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	still waiting on information from patient
Feb-08-2021 10:57:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 2: Opened	Clin: Per Prot Sect 8.13., potential COVID-19 - STREP THROAT (COUGH, SORE THROAT, FEVER) should have please triggered a COVID illness Visit irrespective of perceived etiology, clinical significance and test result and captured on the SOD

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

				form only
Feb-04-2021 07:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN: Positive for Strep Throat- please clarify if there is a positive culture confirming strep.
Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Positive for Strep T hroat	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Mar-09-2021 04:38:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	SDB updated
Mar-08-2021 02:04:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Pending SDB update
Mar-05-2021 10:36:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	PER CRA, NEW SAFETY REPORTED HAS BEEN SUBMITTED WITH THE INFOR ENTERED
Mar-05-2021 10:32:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	SAE RECON: AER#2021086858 ,onset date was recorded as 19JAN2021 in Safety database however, recorded as 17JAN2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Mar-04-2021 13:50:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/17/2021 UNK:UNK	New Information
Mar-04-2021 13:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Mar-04-2021 13:40:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021 UNK:UNK	New Information

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Mar-03-2021 05:43:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON: AER#2021086858 ,onset date was recorded as 19JAN2021 in Safety database however, recorded as 17JAN2021 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Feb-22-2021 16:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 22:11:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/17/2021 UNK:UNK	New Information
Feb-16-2021 21:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-16-2021 21:43:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021 UNK:UNK	New Information
Feb-16-2021 14:52:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical SAE start date is 17Jan21 (date of 1st symptoms); however, SAE report start date is 19Jan21. Please review, harmonize reporting, and update where applicable

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

4. Start Date Time:

Date	Location	User	Value	Reason
Feb-15-2021 21:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/17/2021 UNK:UNK	Transcription Error
Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/19/2021 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Mar-08-2021 10:34:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-05-2021 18:54:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical Thank you; 30Jan21 is the correct End date. The issue is that SAE report has NO end date; please submit this end date in a SAE update
Mar-05-2021 10:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Original value is correct
Mar-05-2021 10:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical End date is 30Jan21; however, SAE update (04Mar21) does not report the event End date. Please submit end date to SAE
Feb-22-2021 16:02:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-16-2021 22:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-16-2021 22:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Jan/30/2021 UNK:UNK	New Information

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Feb-16-2021 14:52:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - Please submit event end date to AE & SAE report if known; also modify to Resolved status if appropriate
Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-16-2021 10:21:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry
Feb-12-2021 04:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: This CRF has not been completed in few fields. Please review and update the page as appropriate.
Feb-09-2021 15:01:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Candidate	Please review the form by Feb 11 to see if form has been updated.
Feb-09-2021 07:18:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	still waiting on information, will update when it comes in
Feb-04-2021 01:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please complete item # 6,7, 9, 10 and 11 to 14. Thank you.

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).

090177e196ae3f14Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Date	Location	User	Value	Reason
Mar-05-2021 10:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Mar-04-2021 13:51:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	CRITERIA IS CORRECT, REPORT HAS BEEN SENT.
Mar-04-2021 07:52:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Opened	CLINICAL - Please review Serious status and update, if appropriate
Feb-26-2021 02:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Deleted	Close Auto Query
Feb-25-2021 19:41:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Group A Streptococcal: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-25-2021 19:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Candidate	For AE Postive for Strept Throat: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-25-2021 19:09:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO Did this serious event require or prolonged hospitalization?  YES Did this serious event result in persistent or significant disability/incapacity?	New Information

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

			NO Is this serious event life threatening?  NO Other medically important serious event  NO	
Feb-24-2021 11:16:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Site has downgraded Strep throat event to no longer be Serious
Feb-22-2021 16:03:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Covid illness workup; Strep throat not a SAE
Feb-16-2021 22:18:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SYMPTOM FOR THIS COVID INNESS VISIT RESOLVED 12-JAN-2021. EMERGENCY ROOM VISIT REPORTED IN SAE WAS MORE THAN 4 DAYS AFTER
Feb-16-2021 22:15:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Feb-16-2021 14:54:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clinical COVID test status (yes/no) during Hosp was not reported in the SAE. Please submit a follow-up SAE form [#2021086858] to document if COVID testing was performed (YES/NO or info not available) and if yes, the date and results.
Feb-16-2021 14:51:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical - Event Serious criteria is NO; however, SAE report submitted with serious criteria = Hospitalization. Please review, harmonize reporting, and update in the appropriate location.

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Feb-16-2021 03:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Postive for Strept Throat: Response to "Is the adverse event serious?" is 'No' but "Serious Adverse Event Number" is present.
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Mar-12-2021 18:02:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-12-2021 18:02:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), t his event is due to:  OTHER  If Other, specify:  Bacterial Infection	New Information
Mar-12-2021 06:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPDCLIN; Was streptococcal infection confirmed in a culture? if yes, cause seems to be bacterial infection. lease review and advise.
Mar-11-2021 12:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Mar-11-2021 12:34:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  UNKNOWN	New Information
Mar-10-2021 04:47:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	GPDCLIN: This section asks about the cause for the AE not the therapy. Please review and update or clarify.
Mar-09-2021 13:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Treatment patient received
Mar-08-2021 04:13:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPDCLIN: Causality listed as "other: antibacterial therapy". Please clarify if you refer to the treatment the subject received rather than the cause and update as applicable.
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  antibacterial therapy	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Feb-02-2021 15:18:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
---	-----------------	---------------------	---------------------------	---------------

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Mar-04-2021 07:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 19:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-25-2021 19:10:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Feb-24-2021 11:15:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clinical - testing would not be considered a 'Non-Drug Treatment'; review if treatment of this type (non-medication) was received and update to NO if none provided

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)



Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Feb-19-2021 13:37:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	She stated she went to the Cleveland Clinic ER on 1/19/2021 where they tested her for strep. Test results came back positive for strep throat. They admitted her for observation overnight where she stated she received IV antibiotics. Coordinators note
Feb-16-2021 14:54:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical - please clarify what is the non-Drug treatment given for the event 'Strep Throat'
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Mar-09-2021 05:35:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-08-2021 22:11:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	data states recovered/resolved in the source.
Mar-08-2021 01:56:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	SAE RECON: Outcome still reported as Recovering/Resolving to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome.
Mar-05-2021 06:46:05 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

Eastern Time (US & Canada)				
Mar-04-2021 13:52:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECOVERED/RESOLVED	New Information
Mar-04-2021 13:42:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Mar-04-2021 13:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE pharyngitis streptococcal: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Mar-04-2021 13:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Mar-04-2021 13:41:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECOVERING/RESOLVING	Transcription Error
Mar-03-2021 05:41:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2021086858,outcome was reported as Recovering/Resolving to Safety DB however, recorded as RECOVERED/RESOLVED on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Feb-17-2021	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY	Query	Auto closed by Validation Check:

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Answered Queries

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

03:53:30 (UTC-05:00) Eastern Time (US & Canada)		(b) (4)	1: Clo sed	VC_AE001_35
Feb-16-2021 22:14:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	Changed data per query
Feb-16-2021 03:50:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW7266552;Response to "What was the outcome of this adverse event?" is 'Recovered/Resolved' or 'Recovered/Resolved with Sequelae' but End Date/Time is missing. Please review and update as appropriate.
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : RECO VERE D/RE SOLV ED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Feb-15-2021 21:23:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Feb-26-2021 02:36:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021086858	Initial Entry
Feb-16-2021 03:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	downgraded to non serious
Feb-04-2021 10:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2021086858	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (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:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-10-2020 00:48:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 07:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-09-2020 07:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/6/2020	Changed Information
Nov-08-2020 02:04:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: As per CRF guidelines, the treatment period is defined as 1st vaccination visit through the 1-month post vaccination visit after the 2nd vaccination. Please update date of EOT to match the date the Visit 3 blood draw.
Oct-23-2020 12:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-23-2020 12:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> VACCINATION	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Oct-23-2020 12:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - Unscheduled

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Feb-23-2021 12:57:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	New Information
Feb-12-2021 19:32:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/12/2021	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: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Feb-12-2021 19:38:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 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	Transcription Error
Feb-12-2021 19:33:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccination 3 Participant is:  eligible and NOT confirmed to have received only placebo at Vaccination 1/2	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**I. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-23-2021 17:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Rivkah Rosen (b) (4)	Query 2: Closed	Response satisfies query
Feb-23-2021 11:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Hello, my understanding and that of the CRA is the date should match when the subject was confirm via email to be unblinded, Also i am unable to make any change because the page is frozen
Feb-23-2021 01:12:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW7351242;Date Treatment Unblinded should be equal to or after DOV in REVAX CONTACT visit when Reason is ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION.Please review and update as appropriate.
Feb-12-2021 19:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-12-2021 19:36:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	Transcription Error
Feb-12-2021 19:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Date Treatment Unblinded" 18/Dec/2021 is a future date relative to when it was entered on 12/Feb /2021. Please correct.

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

Feb-12-2021 19:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2021	Initial Entry
---	-----------------	------------------	-----------------------------------	---------------

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-12-2021 19:32:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR ADDITIO NAL VACCINATION	Initial Entry



**Header Text:** c4591001

**Visit:** V101\_VAX3

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*1. Date of Visit*

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Feb-12-2021 19:39:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/12/2021	Initial Entry

**Header Text:** c4591001

**Visit:** V101\_VAX3

**Form:** INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*I. Consent Was:*

Date	Location	User	Value	Reason
Feb-12-2021 19:39:25 (UTC-05:00) Eastern Time (US & Canada)	ACVOPFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Feb/12/2021	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF  
Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Feb-12-2021 19:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/12/2021	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Feb-12-2021 19:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> REPEAT SCREENING 1	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Feb-12-2021 19:40:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form Version:** 14-Jan-2021 02:21**Site No:** 1030**Subject No:** 10301110**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1030) University Hospital of Cleveland**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Feb/12/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 14-Jan-2021 02:21

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

6.a Sponsor ID:

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Feb-12-2021 19:41:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEGATIVE	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (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: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Data Origin**

Date	Location	User	Value	Reason
Feb-12-2021 19:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-12-2021 19:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-04-2021 13:35:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Mar-04-2021 13:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Mar-04-2021 13:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Mar-04-2021 13:35:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	New Information
Mar-04-2021 06:16:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-03-2021 21:17:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (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: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

				correct as appropriate.
Feb-12-2021 19:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 19:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 19:41:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Feb/12/2021	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 13:35:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> subject's convalescent visit overlapped with her vaccination 3 visits	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-03-2021 21:17:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Feb-12-2021 19:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS7D5V	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 05:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Mar-03-2021 21:17:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-03-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (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:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

21:17:28 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Mar-02-2021 15:02:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Form is not frozen. Please refer to CRF Completion Requirements Section 4.11.2 for instructions on how to delete Add Entry rows.
Mar-02-2021 11:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Please unfreeze so I can delete
Mar-02-2021 05:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7565150;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-12-2021 19:41:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS7D5V	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Mar-03-2021 21:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	Transcription Error
Feb-12-2021 19:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BS7D5W	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: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

5.b Sample ID

Date	Location	User	Value	Reason
Mar-04-2021 05:09:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Mar-03-2021 21:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Mar-03-2021 21:17:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Mar-02-2021 15:02:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Form is not frozen. Please refer to CRF Completion Requirements Section 4.11.2 for instructions on how to delete Add Entry rows.
Mar-02-2021 11:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please unfreeze ecrf so I can update by deleting
Mar-02-2021 05:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7565151;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-12-2021 19:42:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS7D5W	Initial Entry

5.c

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

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (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:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

Feb-19-2021 19:58:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b>	New Information
Feb-12-2021 19:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR8V06	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Feb-19-2021 19:58:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Feb-12-2021 19:42:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8V06	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** V101\_VAX3**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Feb-12-2021 19:43:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Feb-12-2021 19:43:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Feb-12-2021 19:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-12-2021 19:43:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-12-2021 19:43:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Feb/12/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Feb-12-2021 19:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BR8V0D	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Feb-17-2021 03:49:29 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01

**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:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

& Canada)				
Feb-16-2021 21:56:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-16-2021 03:49:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Opened	DMW7266539;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Feb-12-2021 19:43:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8V0D	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: V101\_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Feb/12/2021 13:55	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (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: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

**8. Actual Dose:**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30.0	Initial Entry

**9. Unit:**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ug	Initial Entry

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-12-2021 19:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** V102\_VAX4

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

**Site No:** 1030

**Subject No:** 10301110

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1030) University Hospital of Cleveland

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*I. Date of Visit*

Date	Location	User	Value	Reason
Mar-04-2021 13:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/4/2021	Initial Entry

**Header Text:** c4591001**Visit:** V102\_VAX4**Form Version:** 14-Jan-2021 02:21**Site No:** 1030**Subject No:** 10301110**Generated By:** (b) (4)**Form:** LAB URINALYSIS - PREGNANCY TEST - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1030) University Hospital of Cleveland**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Lab Panel:**

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINALYSIS	Initial Entry

**2. Lab Sub-Panel:**

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> PREGNANCY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/4/2021	Initial Entry

**4. Laboratory Name and Address (Derived)**

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> STUDY SITE	Initial Entry

**5. Specimen Type:**

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> URINE	Initial Entry

**6.a**

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 113 <b>Test::</b> Choriogonadotropin Beta_PX113 <b>Result::</b> NEGATIVE <b>Not Done::</b>	Initial Entry



Header Text: c4591001

Visit: V102\_VAX4

Form Version: 14-Jan-2021 02:21

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

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

Form Status: Data Complete, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

6.a Sponsor ID:

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 113	Initial Entry

6.a Test:

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Choriogonadotropin Beta_PX113	Initial Entry

6.a Result:

Date	Location	User	Value	Reason
Mar-04-2021 13:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEGATIVE	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001**Visit:** V102\_VAX4**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1030**Site Name:** (1030) University Hospital of Cleveland**Subject No:** 10301110**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Mar-04-2021 13:37:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Mar-04-2021 13:37:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-04-2021 13:37:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-04-2021 13:37:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Mar/4/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BR8V10	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR8V10	Initial Entry

Header Text: c4591001

Visit: V102\_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1030

Subject No: 10301110

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1030) University Hospital of Cleveland

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BNT162b2	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Mar/4/2021 09:20	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59	ACV0PFEINFP6000	auto calc	<u>Data Entry:</u>	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: V102\_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

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

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-04-2021 13:38:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Verified

Site No: 1030

Site Name: (1030) University Hospital of Cleveland

Subject No: 10301110

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 04:44

[Back to Form](#)

**1. Subject Status**

Date	Location	User	Value	Reason
Oct-23-2020 12:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-18-2020 19:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-18-2020 13:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENED	Initial Entry

**2. Subject Status Date**

Date	Location	User	Value	Reason
Feb-04-2021 12:21:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	SAE entered on Log form
Feb-03-2021 20:58:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	still waiting for for medical authorization form to be completed by participant.
Feb-02-2021 12:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2021086858 Strep throat(onset date:19Jan2021)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-09-2020 07:28:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Nov/6/2020	Changed Information
Oct-23-2020 12:04:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Initial Entry
Sep-18-2020 19:59:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/18/2020	Initial Entry
Sep-18-2020 13:03:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sep/18/2020	Initial Entry

090177e196ae3f14\Final\Final On: 01-Apr-2021 05:09 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

**Form Status:** Data Complete, Verified

**Site No:** 1030

**Site Name:** (1030) University Hospital of Cleveland

**Subject No:** 10301110

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 04:44

[Back to Form](#)

*I. Casebook Signature*

Date	Location	User	Value	Reason
Nov-13-2020 16:04:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Robert Salata (b) (4)	<b>Data Entry:</b> Click Here to Enable	Initial Entry