

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** COHORT\_SELECTION

**Form Version:** 30-Jul-2020 21:29

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Cohort Selection**

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

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

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** MAIN INFORMED CONSENT

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Aug/20/2020
----	--------------	--



**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[10971011]
2.	Birth Date:	(b) (6) 1941
3.	Sex:	MALE
4.	Ethnicity:	NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN
5.	Race: (Check X all that apply):	WHITE
6.	Racial Designation:	

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DATE OF VISIT

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Aug/20/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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 _____
----	---	-------------------------

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**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Aug/20/2020
2.	Phase of Disposition:	SCREENING
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[depressive Disorders]
	Start Date:	Nov/20/2019
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Obstructive Sleep Apnea]
	Start Date:	Nov/20/2019
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Transient Cerebral ischemia]
	Start Date:	Jul/9/2019
	Ongoing:	NO End Date: UNK/UNK/2019
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Gout]
	Start Date:	Apr/9/2018
	Ongoing:	YES

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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[BPH]
	Start Date:	Apr/9/2018
	Ongoing:	YES
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hypertension]
	Start Date:	Apr/9/2018
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Hyperlipidemia]
	Start Date:	Apr/9/2018
	Ongoing:	YES
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Atrial Fibrillation]
	Start Date:	Apr/9/2018
	Ongoing:	YES
1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[Diabetes Mellitus Type II]
	Start Date:	Apr/9/2018
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** VITAL SIGNS - BASELINE

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Aug/20/2020
2.	Weight:	[218.0]
3.	Unit:	LB
4.	Height:	[70.0]
5.	Unit:	in
6.	Body Mass Index:	[31.3]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[97.1]
	Unit:	F
	Temperature Location:	ORAL CAVITY

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**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** RANDOMIZATION

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Aug/20/2020
2.	Randomization Number:	[235268]
3.	Randomization Group:	[ ]



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
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	[BN6B8X]
5.b	Sample ID	[BN6B8V]
5.c	Sample ID	[BN6B8W]
5.d	Sample ID	[BL9X5X]
5.e	Sample ID	[BL9X5Z]

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**Header Text:** c4591001  
**Visit:** V1\_DAY1\_VAX1\_L  
**Form Version:** 22-Apr-2020 21:03  
**Site No:** 1097  
**Subject No:** 10971011  
**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site Name:** (1097) Main Street Physician's Care - Waterway  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Aug/20/2020
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	[BN6B8R]
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090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** VACCINATION

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination**

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Aug/20/2020 15:50
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

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**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	YES - REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DATE OF VISIT

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

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

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.g	Symptom:	NEW OR WORSENER MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENER JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** VITAL SIGNS - TEMP

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/9/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[96.5]
	Unit:	F
	Temperature Location:	ORAL CAVITY



**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

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

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.a	Sample ID	[BN6B33]
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090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** VACCINATION

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination**

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

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DATE OF VISIT

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

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

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Vaccination Symptoms Diary - Symptom Resolved Dates**

1.	Were medications to treat fever/pain given on the last day the Subject Diary was completed?	NO
2.a	Symptom:	FEVER
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.b	Symptom:	FATIGUE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.c	Symptom:	HEADACHE
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.d	Symptom:	CHILLS
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.e	Symptom:	VOMITING
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.f	Symptom:	DIARRHEA
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO

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**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L      **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES  
**Form Version:** 21-Aug-2020 02:52      **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1097      **Site Name:** (1097) Main Street Physician's Care - Waterway  
**Subject No:** 10971011      **Subject Initials:** ---  
**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 10:39

2.g	Symptom:	NEW OR WORSENERED MUSCLE PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
2.h	Symptom:	NEW OR WORSENERED JOINT PAIN
	Were fever or systemic symptoms present on the last day the Subject Diary was completed?	NO
3.	Injection Site Location:	DELTOID MUSCLE
4.	Injection Site Body Side:	LEFT
5.a	Injection Site Reaction:	REDNESS
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.b	Injection Site Reaction:	SWELLING
	Were injection site reactions present on the last day the Subject Diary was completed?	NO
5.c	Injection Site Reaction:	PAIN AT INJECTION SITE
	Were injection site reactions present on the last day the Subject Diary was completed?	NO

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**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
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	[BN6BJN]
5.b	Sample ID	[BN6BJP]
5.c	Sample ID	[BN6BJR]
5.d	Sample ID	[BL9XBR]
5.e	Sample ID	[BL9XBS]

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DATE OF VISIT

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

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

Header Text: c4591001

Visit: V4\_MONTH6\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Mar/2/2021
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	[BP2S1X]
5.b	Sample ID	[BP2S1Y]
5.c	Sample ID	[BP2S1Z]
5.d	Sample ID	[BPN9SR]
5.e	Sample ID	[BPN9SS]

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**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** V6\_MONTH24\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** DATE OF VISIT - ILLNESS ONSET  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Date of Visit**

1.	Date of Visit	Sep/29/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 on Sep/29/2020**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Signs and Symptoms**

1.	Date of Assessment:	Sep/29/2020
2.	Date of First Symptom Started:	Sep/19/2020
3.	Symptoms Ongoing?	NO
	Date of Last Symptom Resolved:	Sep/22/2020

**Symptoms**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Symptoms - Other**

5.a	Symptoms - Other Text:	[Generalized weakness]
5.b	Symptoms - Other Text:	[Mild epigastric pain]
5.c	Symptoms - Other Text:	[mild dizziness]

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Sep/20/2020	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** MICROBIOLOGY SPECIMEN  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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[Form Audit Trail](#)

**Microbiology Specimen**

1.	Actual Date of Collection:	Sep/20/2020
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:	NEGATIVE
8.	Comments/Findings/Details:	[CLIA certified laboratory.]
9.	Trade Name Other, Specify:	[CLIA certified lab]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/29/2020
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	[BN6B6W]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** HEALTH CARE UTILIZATION  
on Sep/29/2020**Form Version:** 15-Sep-2020 21:53**Form Status:** Data Complete, Frozen, Not Complete**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
1.c	Physician or Healthcare Professional:	PRIMARY CARE PHYSICIAN
	Occurrence of Visits or Contacts:	NO
1.d	Physician or Healthcare Professional:	URGENT CARE
	Occurrence of Visits or Contacts:	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:	[ ]
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**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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	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>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**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>

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Illness Details**

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	NO
3.	Toxicity Grade:	1

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**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	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    **Form:** ILLNESS DETAILS - SEVERE  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**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: 21-Aug-2020 02:49

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.		[ ]			Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date	Specimen Type	Lab Result			Form Instance
2.	CLINICAL CHEMISTRY	McLeod Seacoast Hospital, 4000 Highway 9 East, Little River, SC 29566	Sep/20/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	[ ]	
					30	Alanine Aminotransferase_PX30	28	
					28	Aspartate Aminotransferase_PX28	30	
					35	Alkaline Phosphatase_PX35	102	
					21	Bilirubin_PX21	1.5	
					47	Blood Urea Nitrogen_PX47	[ ]	
					48	Creatinine_PX48	1.23	

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
3. DELETED					Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	[ ]	
						Alanine Aminotransferase_PX30		
						Aspartate Aminotransferase_PX28		
						Alkaline Phosphatase_PX35		
						Bilirubin_PX21		
						Blood Urea Nitrogen_PX47		
						Creatinine_PX48		

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/29/2020

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Lab Chemistry Details**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Sep/29/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**Lab Chemistry Details**

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[McLeod Seacoast Hospital,4000 Highway 9 East, Little River, SC 29566]
3.	Collection Date:	Sep/20/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[28]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit U/L

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/29/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[30]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[102]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[1.5]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit mg/dL

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[1.23]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit mg/dL

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Sep/29/2020**Form Version:** 10-Oct-2020 15:58**Form Status:** Incomplete, Data Complete, Deleted, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

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

[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Lab Chemistry Details**

1.	Lab Panel:		
2.	Laboratory Name and Address	[ ]	<a href="#">Comments</a>
3.	Collection Date:	//	<a href="#">Comments</a>
4.	Specimen Type:		

**Lab Result**

<b>5.a</b>	Sponsor ID:	[329]
	Test:	<del>C Reactive Protein_PX329</del>
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
<b>5.b</b>	Sponsor ID:	[ ]
	Test:	<del>Alanine Aminotransferase_PX30</del>
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Sep/29/2020

Form Version: 10-Oct-2020 15:58

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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

5.e

Sponsor ID:	[ ]
Test:	<del>Aspartate Aminotransferase_PX28</del>
Result:	[ ]
Not Done:	
LNMT	Low [ ] High [ ] Unit

5.d

Sponsor ID:	[ ]
Test:	<del>Alkaline Phosphatase_PX35</del>
Result:	[ ]
Not Done:	
LNMT	Low [ ] High [ ] Unit

5.e

Sponsor ID:	[ ]
Test:	<del>Bilirubin_PX21</del>
Result:	[ ]
Not Done:	
LNMT	Low [ ] High [ ] Unit

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY on Sep/29/2020

Form Version: 10-Oct-2020 15:58

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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

5.f	Sponsor ID:	[ ]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

5.g	Sponsor ID:	[ ]
	Test:	Creatinine_PX48
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
1.		[]			Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING Hematology

Form Version: 15-Sep-2020 21:55

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date	Specimen Type	Lab Result			Form Instance
2.	HEMATOLOGY	McLeod Seacoast Hospital 4000 Highway 9 E, Little River, SC 29566	Sep/20/2020	BLOOD	<b>Sponsor-Defined Identifier</b>	<b>Test:</b>	<b>Result:</b>	<a href="#">Repeating Pages</a>
					1	Hemoglobin_PX1	14.9	
					2	Hematocrit_PX2	43.7	
					3	Erythrocytes_PX3	5.16	
					5	Platelets_PX5	105	
					7	Leukocytes_PX7	10.29	
					608	Neutrophils_PX608	8.9	
					609	Eosinophils_PX609	0	
					612	Monocytes_PX612	0.7	
					610	Basophils_PX610	0	
					611	Lymphocytes_PX611	0.6	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/29/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Laboratory Data Hematology**

1.	Lab Panel:	
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	//
4.	Specimen Type:	

**Lab Result**

5.	Sponsor ID:	[ ]
	Test:	
	Result:	[ ]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology  
on Sep/29/2020**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY	
2.	Laboratory Name and Address	[McLeod Seacoast Hospital 4000 Highway 9 E, Little River, SC 29566]	<a href="#">Comments</a>
3.	Collection Date:	Sep/20/2020	
4.	Specimen Type:	BLOOD	

**Lab Result**

5.a	Sponsor ID:	[1]	<a href="#">Comments</a>
	Test:	Hemoglobin_PX1	
	Result:	[14.9]	<a href="#">Comments</a>
	Not Done:		<a href="#">Comments</a>
	LNMT	Low [ ] High [ ] Unit g/dL	<a href="#">Comments</a>
5.b	Sponsor ID:	[2]	
	Test:	Hematocrit_PX2	
	Result:	[43.7]	
	Not Done:		
	LNMT	Low [ ] High [ ] Unit %	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit    Form: LOCAL LABORATORY DATA - REPEATING Hematology on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[5.16]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit 10^6/cu mm

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[105]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit 10^3/uL

5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[10.29]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit 10^3/uL

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: LOCAL LABORATORY DATA - REPEATING Hematology on Sep/29/2020

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

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5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[8.9]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit 10^3/uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit 10^3/uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.7]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit 10^3/uL

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**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** LOCAL LABORATORY DATA - REPEATING Hematology on Sep/29/2020

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**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit 10^3/uL

5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[0.6]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit 10^3/uL

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 21-Aug-2020 02:50

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details			Form Instance
1.	Sep/20/2020	Record Identifier:	Systolic:	Diastolic:	<a href="#">Repeating Pages</a>
		1	171	81	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - COVID  
on Sep/29/2020

**Form Version:** 21-Aug-2020 02:50

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

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**Vital Signs**

1.	Date:	Sep/20/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[171]
	Diastolic:	[81]
	Respiratory Rate in respirations/minute:	[20]
	Heart Rate in beats/minute:	[99]

**Header Text:** c4591001

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

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

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date:	Vital Signs Details		Form Instance
1.	Sep/20/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	97.0	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** VITAL SIGNS - PULSE OX ROOM AIR  
on Sep/29/2020

**Form Version:** 21-Aug-2020 02:51

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

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**Vital Signs**

1.	Date:	Sep/20/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[97.0]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	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>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** OXYGENATION PARAMETERS  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	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>

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: CONCOMITANT MEDICATIONS - VASOPRESSORS  
on Sep/29/2020

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

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**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>

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**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Sep/20/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i>  Left upper Lobe pneumonia,	<a href="#">Repeating Pages</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** IMAGING  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

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**Imaging**

1.	Date of Assessment:	Sep/20/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	X-RAY
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Left upper Lobe pneumonia.]

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/29/2020

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

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Date of Visit**

1.	Date of Visit	Oct/29/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

3.	COVID-19 Illness Visit:	COVID_A1
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**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/29/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Oct/29/2020
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	[BPVCMC]
5.b	Sample ID	[BPVCMD]
5.c	Sample ID	[BPVCMF]
5.d	Sample ID	[BL9XGJ]
5.e	Sample ID	[BL9XGK]

**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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** Unplanned - New Unscheduled Visit

**Form:** UNPLANNED VISIT

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Unplanned Assessments**

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



**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled

**Form:** DISPOSITION - TREATMENT

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Disposition - Treatment**

1.	Date of Completion/Discontinuation /Death :	Oct/9/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	COMPLETED
4.	Specify Status:	[ ]

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DISPOSITION - FOLLOW-UP

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

**Disposition - Follow-Up**

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

**Header Text:** c4591001

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

**Form:** DATE OF VISIT - REPEAT SWAB

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	Pneumonia	Sep/20/2020 UNK: UNK	NO End Date Time:  Oct/5/2020 11:00	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	HEAD LACERATION	Sep/20/2020 16:08	NO End Date Time:  Sep/29/2020 UNK:UNK	<a href="#">Repeating Pages</a>

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[1]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[Pneumonia]
4.	Start Date Time:	Sep/20/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Oct/5/2020 11:00
6.	Toxicity Grade:	3
7.	Is the adverse event serious?  If Yes, NOTIFY PFIZER IMMEDIATELY.  Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES  Is this serious event associated with congenital anomaly or birth defect? NO  Did this serious event result in death? NO  Did this serious event require or prolong hospitalization? YES  Did this serious event result in persistent or significant disability/incapacity? NO  Is this serious event life threatening? NO  Other medically important serious event YES
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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** ADVERSE EVENT REPORT

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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: [Pt contracted pneumonia from somewhere]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES
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	[2020365457]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**Adverse Event Report**

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[HEAD LACERATION]
4.	Start Date Time:	Sep/20/2020 16:08
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/29/2020 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).	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: [ACCIDENT IN ER]

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO
12.	Was a Non-Drug Treatment given?	YES
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	[ ]

**Header Text:** c4591001

**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** MEDICATION ERROR

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Medication Error**

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

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** Logs

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Concomitant Medications**

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

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Concomitant Medications**

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

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** RADIATION TREATMENT

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** RADIATION TREATMENT

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Radiation Treatment**

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

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** TRANSFUSIONS

**Form Status:** Not Started

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Vital Signs**

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

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** VACCINATION

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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?	

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** Unplanned Vaccination - Unscheduled

**Form:** CONTACT OUTCOME - MONTH 6

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Contact Outcome**

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



**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** INFORMED CONSENT - ASYMPTOMATIC SURVEILLANCE

**Form Version:** 14-Jan-2021 02:29

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Informed Consent - Asymptomatic Surveillance**

1.	Consent Was:	
----	--------------	--

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**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:** Potential ReVax Initial Contact -  
Unscheduled

**Form:** DATE OF VISIT

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/13/2021
2.	Erroneous Visit	

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[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 and NOT 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:** 1097

**Subject No:** 10971011

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

**Form:** TREATMENT UNBLINDED

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/13/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** WITHDRAWAL OF CONSENT

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Withdrawal Of Consent**

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



**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** DEATH DETAILS CODED

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

**Form Status:** Not Started

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Death Details**

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

**Cause of Death**

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

**Header Text:** c4591001

**Visit:** Subject Status - Unscheduled

**Form:** SUBJECT STATUS

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

**Form Status:** Data Complete, Verified

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Oct/9/2020

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[eCRF Audit Trail History](#)

**Casebook Signature Form**

1.	Casebook Signature	<a href="#">Click Here to Enable</a>
----	--------------------	--------------------------------------

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

[Audit Trail](#)

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Tom Christensen	Approved	Mar-02-2021 12:03:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

By my dated signature below, I, TomChristensen, 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.

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

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

**Form Version:** 30-Jul-2020 21:29

**Site No:** 1097

**Subject No:** 10971011

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

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

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Aug-25-2020 15:32:51 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-09-2020 10:33:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-09-2020 10:33:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-09-2020 10:33:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-09-2020 10:33:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-09-2020 10:33:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-09-2020 10:33:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-09-2020 10:33:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** ILLNESS DETAILS - SEVERE - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

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Item	Date	User	Comment
Form	Nov-02-2020 19:56:58 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

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Item	Date	User	Comment
2	Nov-04-2020 10:03:43 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	not applicable
2	Nov-03-2020 10:01:37 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Nov-02-2020 19:59:46 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
2	Nov-02-2020 19:56:14 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
2	Nov-02-2020 17:00:04 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Duplicate not applicable
			Not Applicable

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

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Item	Date	User	Comment
3	Nov-03-2020 10:03:30 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Nov-03-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable
3	Nov-03-2020 10:02:17 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	
3	Nov-02-2020 20:00:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Nov-09-2020 09:17:11 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Normal ranges not available for hematology collected 20-sep-2020.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-26-2020 09:40:31 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Information is not copied and pasted. Information has been entered manually numerous times.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-26-2020 09:31:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Range not available on lab report.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-26-2020 09:31:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Range not available on lab report.



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-26-2020 09:31:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Range not available on lab report.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5.a	Oct-26-2020 09:31:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Range not available on lab report.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-09-2020 11:23:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** OXYGENATION PARAMETERS - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-09-2020 11:23:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** OXYGENATION PARAMETERS - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-09-2020 11:23:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** OXYGENATION PARAMETERS - Comments  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-09-2020 11:23:23 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
Form	Oct-09-2020 11:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
1	Oct-09-2020 11:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
2	Oct-09-2020 11:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
3	Oct-09-2020 11:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
4	Oct-09-2020 11:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
5	Oct-09-2020 11:29:53 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - Comments

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Item	Date	User	Comment
6	Oct-09-2020 11:29:53 (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, Signed, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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

- CRF\_Sign

Name	Signature Meaning	Date	Type	Action
Tom Christensen	Approved	Mar-02-2021 12:03:48 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed

**Affidavit:**

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

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

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

(b) (6)	N/A	Mar-02-2021 09:18:44 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Feb-24-2021 16:17:56 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, 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	Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Jan-20-2021 20:32:42 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**Affidavit:**

By my dated signature below, I, TomChristensen, 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-06-2021 15:34:30 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Nov-16-2020 17:19:16 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-06-2020 08:07:08 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Nov-05-2020 19:43:06 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

**Header Text:** c4591001**Visit:** Investigator Signature - Unscheduled**Form:** CASEBOOK SIGNATURE FORM - Signature History**Form Version:** 22-Apr-2020 21:04**Form Status:** Data Complete, Signed, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

(b) (6)	N/A	Nov-03-2020 10:01:37 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Nov-02-2020 20:11:29 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Nov-02-2020 09:38:26 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Oct-30-2020 14:48:55 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

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

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

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

(b) (6)	N/A	Oct-30-2020 08:32:22 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Oct-27-2020 11:11:20 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**Affidavit:**

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

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

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

(b) (6)	N/A	Oct-23-2020 08:17:46 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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**Affidavit:**

N/A

Tom Christensen	Approved	Oct-22-2020 16:08:34 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, TomChristensen, 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.

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: COHORT SELECTION - eCRF Audit Trail History

Form Version: 30-Jul-2020 21:29

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Select appropriate response - Protocol version**

Date	Location	User	Value	Reason
Aug-21-2020 16:47:46 (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
Aug-21-2020 20:55:06 (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:** 1097

**Subject No:** 10971011

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

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Consent Was:**

Date	Location	User	Value	Reason
Aug-21-2020 20:59:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Aug/20/2020	Initial Entry

**Header Text:** c4591001**Visit:** COHORT\_SELECTION**Form Version:** 06-Jul-2020 21:55**Site No:** 1097**Subject No:** 10971011**Generated By:** (b) (4)**Form:** DEMOGRAPHY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Subject ID**

Date	Location	User	Value	Reason
Sep-22-2020 21:32:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Event entered in AE CRF
Sep-22-2020 12:03:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	2020365457
Sep-22-2020 06:23:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020365457 Pneumonia (onset date:20Sep2020)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.
Aug-21-2020 16:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10971011	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-23-2020 10:06:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-23-2020 09:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-23-2020 09:50:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> (b) (6) 1941	Transcription Error
Sep-23-2020 04:40:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Charu Sabharwal (b) (4)	Query 1: Reissued:Opened	Clinical_please update birth date in the EDC.

Header Text: c4591001

Visit: COHORT\_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 06-Jul-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Sep-22-2020 15:20:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	(b) (6) 1941 is correct
Sep-22-2020 14:51:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	ClinQuery: birthday in SAE narrative is reported as (b) (6) 1941; please confirm which date is correct and update in the appropriate location
Aug-21-2020 16:47:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Feb/4/1952	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Aug-26-2020 02:22:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Cl osed	Response satisfies query
Aug-25-2020 15:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: An swered	Initial Entry
Aug-25-2020 15:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : MALE	Initial Entry
Aug-22-2020 03:32:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Op ened	As per Impala, Sex is recorded as Male. Please review and update as appropriate. (b) (4)

4. Ethnicity:

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Aug-25-2020 15:32:16 (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
Aug-25-2020 15:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date of Visit**

Date	Location	User	Value	Reason
Aug-25-2020 15:32:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Aug-25-2020 15:33:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Aug-25-2020 15:33:12 (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
Aug-25-2020 15:33:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form Version:** 22-Apr-2020 21:03**Site No:** 1097**Subject No:** 10971011**Generated By:** (b) (4)**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1.a**

Date	Location	User	Value	Reason
Aug-25-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 1 <b>Medical History Term:</b> depressive Disorders <b>Start Date:</b> Nov/20/2019 <b>Ongoing:</b> YES	Initial Entry

**1.a Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> depressive Disorders	Initial Entry

**1.a Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/20/2019	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 15:34:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

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Date	Location	User	Value	Reason
Aug-25-2020 15:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Num</b> 2 <b>er:</b> <b>Medical History</b> Obstructive Slee <b>Term:</b> p Apnea <b>Start Date:</b> Nov/20/2019 <b>Ongoing:</b> YES	Initial Entry

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 15:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Obstructive Sleep Apnea	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/20/2019	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 15:35:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.c**

Date	Location	User	Value	Reason
Sep-04-2020 13:01:05 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Line/MH Nu</b> 3	New Information

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)		(b) (4), (b) (6)	<b>mber:</b> <b>Medical Hist</b> Transient Cerebra <b>ory Term:</b> l ischemia <b>Start Date:</b> Jul/9/2019 <b>Ongoing:</b> NO End Date:  UNK/UNK/20 19	
Aug-25-2020 15:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Nu</b> 3 <b>mber:</b> <b>Medical Histo</b> Transient Cerebr <b>ry Term:</b> al ischemia <b>Start Date:</b> Jul/9/2019 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

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***1.c Line/MH Number:***

Date	Location	User	Value	Reason
Aug-25-2020 15:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

***1.c Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-04-2020 14:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Thank you for adding end date into eCRF for the condition
Sep-04-2020 12:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is not ongoing
Sep-03-2020 16:34:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Transient Cerebral Ischemia is reported with no end date. Per definition symptoms of the event lasting <24 hours. Please confirm if still ongoing, else specify an end date for this condition. Thanks
Aug-25-2020 15:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Transient Cerebral ischemia	Initial Entry

***1.c Start Date:***

Date	Location	User	Value	Reason
Aug-25-2020 15:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jul/9/2019	Initial Entry

***1.c Ongoing:***

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-04-2020 13:01:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date:  UNK/UNK/2019	New Information
Aug-25-2020 15:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

*1.d*

Date	Location	User	Value	Reason
Aug-25-2020 15:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Line/MH Number:</b> 4 <b>Medical History Term</b> Gout : <b>Start Date:</b> Apr/9/201 8 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

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**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 4	Initial Entry

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Gout	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Apr/9/2018	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 5 Medical History Term BPH : Start Date: Apr/9/2018 8 Ongoing: YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

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**1.e Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**1.e Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPH	Initial Entry

**1.e Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/9/2018	Initial Entry

**1.e Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 15:36:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.f**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Line/MH Number: 6 Medical History Term: Hypertension Start Date: Apr/9/2018 Ongoing: YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

**1.f Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**1.f Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hypertension	Initial Entry

**1.f Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/9/2018	Initial Entry

**1.f Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.g**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH Number:</b> 7 <b>Medical History Term:</b> Hyperlipidemia <b>Start Date:</b> Apr/9/2018 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

**1.g Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

**1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Hyperlipidemia	Initial Entry

**1.g Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Apr/9/2018	Initial Entry

**1.g Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 15:37:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**1.h**

Date	Location	User	Value	Reason
Aug-25-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 8 Medical History Term: Atrial Fibrillation Start Date: Apr/9/2018 Ongoing: YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

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Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

**1.h Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 8	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Atrial Fibrillation	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Apr/9/2018	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 15:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

**1.i**

Date	Location	User	Value	Reason
Sep-01-2020 17:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Line/MH Number: 9 Medical History Term: Diabetes Mellitus Type II Start Date: Apr/9/2018 Ongoing: YES	Transcription Error
Aug-25-2020 15:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Line/MH Number: 9	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			<b>Medical History</b> Diabetes Me <b>Term:</b> llitus <b>Start Date:</b> Apr/9/2018 <b>Ongoing:</b> YES	
--	--	--	---	--

**1.i Line/MH Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-03-2020 19:42:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Closed	Response satisfies query
Sep-01-2020 17:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:03

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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

Date	Location	User	Value	Reason
Sep-01-2020 17:35:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Diabetes Mellitus Type II	Transcription Error
Sep-01-2020 02:02:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	GPD CLIN: Please specify if Type I or II diabetes in the medical history term if known. Thank you.
Aug-31-2020 03:57:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Katherine Liau (b) (4)	Query 1: Candidate	GPD CLIN: Please specify if Type I or II diabetes in the medical history term if known. Thank you.
Aug-25-2020 15:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Diabetes Mellitus	Initial Entry

**1.i Start Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Apr/9/2018	Initial Entry

**1.i Ongoing:**

Date	Location	User	Value	Reason
Aug-25-2020 15:38:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date:**

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aug/20/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 218.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> LB	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 70.0	Initial Entry

**5. Unit:**

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> in	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 31.3	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

7.a

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier 1 : Temperature: 97.1 Temperature Unit: F Temperature Location: ORAL CAVITY	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (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
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.1	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Aug-25-2020 15:39:47 (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
Aug-25-2020 15:39:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Aug-25-2020 15:40:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Aug-25-2020 15:40:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 235268	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 15:41:17 (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
Aug-25-2020 15:41:17 (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
Aug-25-2020 15:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 15:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 15:41:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-25-2020 15:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6B8X	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: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6B8X	Initial Entry

5.b

Date	Location	User	Value	Reason
Aug-25-2020 15:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN6B8V	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6B8V	Initial Entry

5.c

Date	Location	User	Value	Reason
Aug-25-2020 15:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN6B8W	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:44:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6B8W	Initial Entry

5.d

Date	Location	User	Value	Reason
Aug-25-2020 15:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9X5X	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:45:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9X5X	Initial Entry

5.e

Date	Location	User	Value	Reason
Aug-25-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9X5Z	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Aug-25-2020 15:45:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9X5Z	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (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:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Aug-25-2020 15:46:07 (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
Aug-25-2020 15:46:07 (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
Aug-25-2020 15:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Aug-25-2020 15:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Aug-25-2020 15:46:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Aug/20/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Aug-25-2020 15:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6B8R	Initial Entry

**Header Text:** c4591001

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

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

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Aug-25-2020 15:46:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6B8R	Initial Entry

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Aug-25-2020 15:47:24 (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
Aug-25-2020 15:47:24 (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
Aug-25-2020 15:47:24 (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
Aug-25-2020 15:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aug/20/2020 15:50	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Aug-25-2020 15:47:24 (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
Aug-25-2020 15:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

7. Route:

Date	Location	User	Value	Reason
Aug-25-2020 15:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Aug-25-2020 15:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPECIFIED OB SERVATION PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Aug-25-2020 15:47:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form Version: 06-Jul-2020 21:53

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Select appropriate response - Reactogenicity diary collection**

Date	Location	User	Value	Reason
Sep-02-2020 04:18:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-01-2020 17:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Sep-01-2020 17:35:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES - REACTOGENICITY E -DIARY COLLECTED FOR THIS SUBJECT	Transcription Error
Sep-01-2020 06:47:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	eDiary: REACTOGENICITY E-DIARY COLLECTED FOR THIS SUBJECT is 'No' however VAX 1 eDiary records are available for the subject. Please verify and update. Else, confirm in query response appropriately.
Aug-25-2020 15:48:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGENICITY E- DIARY NOT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date of Visit**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-12-2020 11:41:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: FE VE R Were fever or systemic sy N mptoms present on the las O t day the Subject Diary w as completed?:	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: FA TI GU	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			E	
			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	

2.b Symptom:

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FATIGUE	Initial Entry

2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2.c

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

**2.c Symptom:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS Were fever or systemic sy NO mptoms present on the las t day the Subject Diary w as completed?:	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

**2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING <b>Were fever or systemic s</b> NO <b>ymptoms present on the l</b> <b>ast day the Subject Diar</b> <b>y was completed?:</b>	Initial Entry
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**2.e Symptom:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A <b>Were fever or systemic s</b> NO <b>ymptoms present on the l</b> <b>ast day the Subject Diary</b> <b>was completed?:</b>	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

**2.f Symptom:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

**2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <b>Symptom:</b> NEW OR WORSE NED MU SCLE PA IN  <b>Were fever or syste NO mic symptoms prese nt on the last day th e Subject Diary was completed?:</b>	Initial Entry

**2.g Symptom:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR WORSE NED MUSC LE PAIN	Initial Entry

**2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.h

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSENEDED JOINT PAIN  <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENEDED JOINT PAIN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Sep-12-2020 11:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SW ELL ING  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

Visit: V2\_VAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.b Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> SWELLING	Initial Entry

5.b Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Injection Site Reaction: PAIN AT INJECTION SITE  Were injection site reactions present on the last day the Subject Diary was completed?: NO	Initial Entry

5.c Injection Site Reaction:

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> PAIN AT INJECTION SITE	Initial Entry

5.c Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Sep-12-2020 11:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



**Header Text:** c4591001**Visit:** V2\_VAX2\_L**Form Version:** 21-Aug-2020 02:51**Site No:** 1097**Subject No:** 10971011**Generated By:** (b) (4)**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-12-2020 11:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier 1</b> :: <b>Temperature:</b> 96.5 <b>Temperature Uni F</b> <b>t:</b> <b>Temperature Loc ORAL CA</b> <b>ation::</b> VITY	Transcription Error
Sep-12-2020 11:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier 1</b> :: <b>Temperature:</b> 95.5 <b>Temperature Uni F</b> <b>t:</b> <b>Temperature Loc ORAL CA</b> <b>ation::</b> VITY	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:58 (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
Sep-13-2020 05:31:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 21-Aug-2020 02:51

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

Sep-12-2020 11:43:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	DATA IS CVORRECT. NOT CLINICALLY SIGNIFICANT
Sep-12-2020 11:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 96.5 F is outside of Normal Range 97 - 99.5 F.
Sep-12-2020 11:43:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 96.5	Transcription Error
Sep-12-2020 11:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Temperature 95.5 F is outside of Normal Range 97 - 99.5 F.
Sep-12-2020 11:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 95.5	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-12-2020 11:42:58 (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
Sep-12-2020 11:42:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (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:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-12-2020 11:44:12 (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-12-2020 11:44:12 (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-12-2020 11:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-12-2020 11:44:12 (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-12-2020 11:44:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/9/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-12-2020 11:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6B33	Initial Entry

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-12-2020 11:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6B33	Initial Entry

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-12-2020 11:45:25 (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-12-2020 11:45:25 (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-12-2020 11:45:25 (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-12-2020 11:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/9/2020 09:05	Initial Entry

**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-12-2020 11:45:25 (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-12-2020 11:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V2\_VAX2\_L

Form Version: 22-Apr-2020 21:04

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

7. Route:

Date	Location	User	Value	Reason
Sep-12-2020 11:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-12-2020 11:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> THE PROTOCOL SPECIFIED OB SERVATION 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-12-2020 11:45:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-16-2020 05:16:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-15-2020 14:32:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-15-2020 02:23:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Please clarify, EOT and Visit 3 date is not matching. Thank you.
Oct-09-2020 12:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Were medications to treat fever/pain given on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FE VE R <b>Were fever or systemic symptoms present on the last day the Subject Diary was completed?:</b> N O	Initial Entry

**2.a Symptom:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FEVER	Initial Entry

**2.a Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.b**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> FA TIG UE	Initial Entry



**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History  
**Form Version:** 21-Aug-2020 02:52 **Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1097 **Site Name:** (1097) Main Street Physician's Care - Waterway  
**Subject No:** 10971011 **Subject Initials:** ---  
**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 10:39

			Were fever or systemic symptoms present on the last day the Subject Diary was completed?:	
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**2.b Symptom:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> FATIGUE	Initial Entry

**2.b Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.c**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom:: HE AD AC HE Were fever or systemic symptoms present on the last day the Subject Diary was completed?: NO	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED  
DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

**2.c Symptom:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> HEADACHE	Initial Entry

**2.c Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.d**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptom:: CH IL LS  Were fever or systemic sym NO ptoms present on the last da y the Subject Diary was co mpleted?:	Initial Entry

**2.d Symptom:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> CHILLS	Initial Entry

**2.d Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**2.e**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> VO MIT ING  <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry
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**2.e Symptom:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> VOMITING	Initial Entry

**2.e Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.f**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> DIA RR HE A  <b>Were fever or systemic sy mptoms present on the last day the Subject Diary was completed?:</b>	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**2.f Symptom:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> DIARRHEA	Initial Entry

**2.f Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2.g**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom:</b> NEW OR WORSE NED MUS CLE PAI N  <b>Were fever or system NO ic symptoms present on the last day the Su bject Diary was comp leted?:</b>	Initial Entry

**2.g Symptom:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSE NED MUSCLE PAIN	Initial Entry

**2.g Were fever or systemic symptoms present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

2.h

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptom::</b> NEW OR WORSE NED JOI NT PAIN  <b>Were fever or systemi c symptoms present o n the last day the Sub ject Diary was comple ted?:</b> NO	Initial Entry

2.h Symptom:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR WORSENERD JOINT PA IN	Initial Entry

2.h Were fever or systemic symptoms present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

3. Injection Site Location:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

4. Injection Site Body Side:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

Form: VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:52

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> RE DN ESS  <b>Were injection site reaction NO s present on the last day th e Subject Diary was compl eted?:</b>	Initial Entry

5.a Injection Site Reaction:

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> REDNESS	Initial Entry

5.a Were injection site reactions present on the last day the Subject Diary was completed?

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction::</b> SWE LLI NG  <b>Were injection site reactio NO ns present on the last day t he Subject Diary was com pleted?:</b>	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** V3\_MONTH1\_POSTVAX2\_L**Form:** VACCINATION SYMPTOMS DIARY - SYMPTOM RESOLVED DATES - eCRF Audit Trail History**Form Version:** 21-Aug-2020 02:52**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**5.b Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWELLING	Initial Entry

**5.b Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Injection Site Reaction:</b> PAIN AT INJECTION SITE  <b>Were injection site reactions present on the last day the Subject Diary was completed?:</b> NO	Initial Entry

**5.c Injection Site Reaction:**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PAIN AT INJECTION SITE	Initial Entry

**5.c Were injection site reactions present on the last day the Subject Diary was completed?**

Date	Location	User	Value	Reason
Oct-09-2020 12:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	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: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Oct-09-2020 12:54:07 (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 12:54:07 (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
Jan-07-2021 11:27:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-06-2021 15:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	updated
Jan-06-2021 11:57:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	HOLDS: For visit 3, the lab has received serum sample barcodes BL9XBS,BL9XBR; however, the barcodes have not been recorded for this visit. Please review and update as appropriate. Otherwise please clarify.
Oct-09-2020 12:54:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-09-2020 12:54:07 (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 12:54:07 (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

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

Date	Location	User	Value	Reason
Jan-06-2021 15:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-09-2020 12:54:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6BJN	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 12:54:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6BJN	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 12:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6BJP	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.b Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 12:55:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6BJP	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 12:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BN6BJR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Oct-09-2020 12:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BN6BJR	Initial Entry

5.d

Date	Location	User	Value	Reason
Jan-06-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9XBR	Transcription Error
Jan-06-2021 15:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9XBRQ	Initial Entry
Oct-12-2020 16:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID:	Transcription Error
Oct-09-2020 12:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9XBS	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Jan-06-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-06-2021 15:37:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9XBR	Transcription Error
Jan-06-2021 15:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Jan-06-2021 15:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Barcode contains unexpected characters (Q, A, E, I, O, or U). Please review and correct as appropriate.
Jan-06-2021 15:34:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9XBRQ	Initial Entry
Oct-12-2020 21:59:44	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check:

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001  
**Visit:** V3\_MONTH1\_POSTVAX2\_L  
**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History  
**Form Version:** 22-Apr-2020 21:03  
**Form Status:** Data Complete, Locked, Frozen, Verified  
**Site No:** 1097  
**Site Name:** (1097) Main Street Physician's Care - Waterway  
**Subject No:** 10971011  
**Subject Initials:** ---  
**Generated By:** (b) (4)  
**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-05:00) Eastern Time (US & Canada)			ed	VC_BEETRK001_01
Oct-12-2020 16:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-12-2020 16:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Transcription Error
Oct-09-2020 15:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 1: Opened	DMW4937027;This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-09-2020 12:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BL9XBS	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Jan-06-2021 15:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sample ID: BL9XBS	Transcription Error
Jan-06-2021 15:35:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sample ID: BL9XBSR	Initial Entry
Oct-12-2020 16:33:35 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Sample ID:	Transcription Error

**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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)				
Oct-09-2020 12:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9XBS	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: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.e Sample ID

Date	Location	User	Value	Reason
Jan-06-2021 15:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Jan-06-2021 15:37:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9XBS	Transcription Error
Jan-06-2021 15:35:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Barcode is not 6 characters in length. Please review and correct as appropriate.
Jan-06-2021 15:35:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9XBSR	Initial Entry
Oct-12-2020 21:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Closed	Auto closed by Validation Check: VC_BEETRK001_01
Oct-12-2020 16:33:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-12-2020 16:33:35	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-05:00) Eastern Time (US & Canada)				
Oct-09-2020 15:43:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Open ed	DMW4937028; This Barcode is already recorded more than once (for the same subject). Please review and update as appropriate.
Oct-09-2020 12:57:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9XBS	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_L

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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***1. Date of Visit***

Date	Location	User	Value	Reason
Mar-05-2021 03:54:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed per SITE response, added to PD tracker for Clinical Review
Mar-04-2021 08:40:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this is correct noted in source, pt elderly and had appt with PCP
Mar-04-2021 03:39:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: Date of visit at V4_MONTH6_L is out of window for -1 days from V2_VAX2_L DOV or V2 Vaccination date. Please verify and update. Else, confirm in query response appropriately.
Mar-02-2021 09:18:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/2/2021	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

Visit: V4\_MONTH6\_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: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Data Origin**

Date	Location	User	Value	Reason
Mar-02-2021 09:19:08 (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-02-2021 09:19:08 (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-02-2021 09:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-02-2021 09:19:08 (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-02-2021 09:19:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Mar/2/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Mar-02-2021 09:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BP2S1X	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_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: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.a Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 09:19:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP2S1X	Initial Entry

5.b

Date	Location	User	Value	Reason
Mar-02-2021 09:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP2S1Y	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 09:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP2S1Y	Initial Entry

5.c

Date	Location	User	Value	Reason
Mar-02-2021 09:20:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BP2S1Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 09:20:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BP2S1Z	Initial Entry

5.d

Date	Location	User	Value	Reason
Mar-02-2021 09:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BPN9SR	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: V4\_MONTH6\_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: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 09:20:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPN9SR	Initial Entry

5.e

Date	Location	User	Value	Reason
Mar-02-2021 09:20:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPN9SS	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Mar-02-2021 09:20:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPN9SS	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History on Sep/29/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Visit**

Date	Location	User	Value	Reason
Sep-29-2020 15:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Sep-29-2020 15:37:25 (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.
Sep-29-2020 15:37:25 (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 missing. Please review and update as appropriate.
Sep-29-2020 15:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 15:37:25 (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 Sep/29/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1097**Subject No:** 10971011**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Date of Assessment:**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/19/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Sep/22/2020	Initial Entry

**4.a**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: FEVER Symptom Present: NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (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
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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4.b

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW OR INCREASED COUGH Symptom P YES resent:	Initial Entry

4.b Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (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
Sep-29-2020 15:47:52 (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
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: NO	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form Version:** 15-Sep-2020 21:55**Site No:** 1097**Subject No:** 10971011**Generated By:** (b) (4)**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39**4.c Symptoms:**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SHORTN ESS OF BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (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
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: CHILLS Symptom Present: YES	Initial Entry

**4.d Symptoms:**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (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
Sep-29-2020 15:47:52 (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
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW OR INCREASE : D MUSCLE PAIN	Initial Entry



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			Symptom NO Present:	
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4.e Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.f

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: NEW LOSS OF TASTE OR SMELL  Symptom NO Present:	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.g

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms NEW OR INCREASE : D SORE THROAT <b>Symptom NO</b> <b>Present:</b>	Initial Entry

4.g Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREASED SORE TH ROAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms: DIARRHEA <b>Symptom Present: NO</b>	Initial Entry

4.h Symptoms:

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (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
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/29/2020**Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF  
Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**4.i**

Date	Location	User	Value	Reason
Sep-29-2020 15:47:52 (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
Sep-29-2020 15:47:52 (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
Sep-29-2020 15:47:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-29-2020 15:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Generalized weakness	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Sep-29-2020 15:48:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Generalized weakness	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Sep-29-2020 15:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms - Other:</b> Mild epigastric pain	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.b Symptoms - Other Text:

Date	Location	User	Value	Reason
Sep-29-2020 15:49:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mild epigastric pain	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-29-2020 15:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms - Other mild dizziness	Initial Entry

5.c Symptoms - Other Text:

Date	Location	User	Value	Reason
Sep-29-2020 15:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mild dizziness	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - Audit Trail  
on Sep/29/2020

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

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Sep-29-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/29/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Sep-29-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/20/2020	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Sep-29-2020 15:51:42 (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
Sep-29-2020 15:51:42 (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
Sep-29-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RESP SYNDRO ME CORONAVIRUS 2	Initial Entry

**5. Device Type:**

Date	Location	User	Value	Reason
Sep-29-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGNOSTIC TES T	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Oct-02-2020 02:21:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/29/2020**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-01-2020 09:55:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unknown
Sep-30-2020 04:33:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thanks for the response. Kindly consider updating Unknown under OTHER SPECIFY field. Thank you.
Sep-29-2020 15:52:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Trade name unknown.
Sep-29-2020 15:52:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Trade Name is Other, however Trade Name Other, Specify is not completed. Please update.
Sep-29-2020 15:52:16 (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
Sep-29-2020 15:51:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Oct-06-2020 15:54:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CLIA certified laboratory.	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Oct-07-2020 12:19:43	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History on Sep/29/2020**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		query
Oct-07-2020 08:16:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-07-2020 08:16:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CLIA certified lab	Changed Information
Oct-07-2020 06:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Thank you for the response. However, as per the response if it is CLIA- certified laboratory then please including the text 'CLIA-certified lab' in the required field. Else clarify.
Oct-06-2020 15:53:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	It was done at McLeod Seacoast Hospital so I feel sure that it is a CLIA certified laboratory.
Oct-05-2020 11:49:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM : Please indicate whether the test was conducted in a CLIA- certified laboratory by including the text 'CLIA-certified lab' in the required field.
Oct-01-2020 09:55:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> unknown	Initial Entry



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-29-2020 15:53:26 (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-29-2020 15:53:26 (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
Sep-29-2020 15:56:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Sep-29-2020 15:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: 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.
Sep-29-2020 15:53:26 (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
Sep-29-2020 15:56:49 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> patient did not do it.	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)

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

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Sep-29-2020 15:53:55 (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-29-2020 15:53:55 (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-16-2020 03:17:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per site response
Oct-14-2020 09:25:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	22Sep2020 is correct
Oct-13-2020 04:32:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thanks for response. Please verify and confirm Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Else clarify.
Oct-12-2020 16:42:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject did not have COVID. Subject did have pneumonia. Chest X-ray on 10-5-2020 Showed Pneumonia resolved.

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1097**Subject No:** 10971011**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-12-2020 05:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Date of Collection is more than 4 days after Date of Last Symptom Resolved on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Sep-29-2020 15:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 15:53:55 (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-29-2020 15:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Sep/29/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-29-2020 15:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BN6B6W	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-29-2020 15:54:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6B6W	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/29/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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1.a

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: SPECIALIST Occurrence of Visits or NO Contacts:	Initial Entry

1.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SPECIALIST	Initial Entry

1.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

1.b

Date	Location	User	Value	Reason
Oct-16-2020 09:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: EMERGENCY ROOM Occurrence of YES Visits or Contacts: Number of Visits or Contacts: 1	Transcription Error
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: EMERGENCY ROOM	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/29/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			Occurrence of Vi NO sits or Contacts:	
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**1.b Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> EMERGENCY ROOM	Initial Entry

**1.b Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Oct-18-2020 22:23:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 09:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-16-2020 09:59:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES <i>Number of Visits or Contacts:</i>  1	Transcription Error
Oct-16-2020 09:00:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Subject was seen in emergency room before hospitalization on 20 Sep 2020 for pneumonia and tested for SARs-CoV-2. Please consider this healthcare utilization for potential COVID illness, and update as required.
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/29/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

*I.c*

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: NO	Initial Entry

*I.c Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (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
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

*I.d*

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: URGENT CARE Occurrence of Visits or Contacts: NO	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/29/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

**1.d Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> URGENT CARE	Initial Entry

**1.d Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.e**

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry

**1.e Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> TELEPHONE CONSULTATION	Initial Entry

**1.e Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**1.f**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/29/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Type of Practitioner: OTHE R Occurrence of Visits or C NO ontacts:	Initial Entry
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**1.f Physician or Healthcare Professional:**

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**1.f Occurrence of Visits or Contacts:**

Date	Location	User	Value	Reason
Sep-29-2020 15:55:31 (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
Nov-06-2020 13:14:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 08:07:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Nov-06-2020 08:07:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Nov-06-2020 03:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Opened	Other Type of Practitioner Specify” is expected to be completed only when the “Type of Practioner” is OTHER and response for “Occurrence of

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History on Sep/29/2020

Form Version: 15-Sep-2020 21:53

Form Status: Data Complete, Frozen, Not Complete

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

				Visits or Contacts" is answered as Yes. Hence, please verify and remove the specification comment if not relevant
Sep-29-2020 15:56:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> none	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Oct-26-2020 16:07:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 10:00:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Everyone that goes into the hospital for admission or any other reason is tested. He did not have COVID.
Oct-16-2020 08:58:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINICAL Subject was hospitalized on 20 Sep 2020 for pneumonia and tested for SARs-CoV-2. Please consider this healthcare utilization for potential COVID illness, and update as required.
Sep-29-2020 15:55:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History on Sep/29/2020**Form Version:** 06-Jul-2020 21:53**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Oct-09-2020 10:33:04 (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
Oct-09-2020 10:33:04 (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
Oct-09-2020 10:33:04 (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
Oct-09-2020 10:33:04 (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
Oct-09-2020 10:33:04 (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
Oct-09-2020 10:33:04 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit    **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History  
on Sep/29/2020

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)				
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090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** ILLNESS DETAILS - eCRF Audit Trail History  
on Sep/29/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Sep-29-2020 15:57:52 (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
Oct-08-2020 07:54:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-07-2020 16:50:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Patiewnt symptoms related to pneumonia not COVID
Oct-07-2020 09:12:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	RE-QUERY: CLIQUEY:Per CRF CRs Section 8.33.5, please enter worst toxicity grade (1 to 5) as it relates to reported symptom(s) on SOD CRF.
Oct-07-2020 08:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Covid test negative.
Oct-07-2020 07:59:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLIQUEY: As subject is symptomatic, per CCG's toxicity grade from 1-5 should be entered. Please update.
Sep-29-2020 15:57:52 (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 Form: ILLNESS DETAILS - eCRF Audit Trail History on Sep/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-07-2020 16:49:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1	Initial Entry
Oct-07-2020 08:24:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	C0vid test negative.
Oct-02-2020 02:22:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-01-2020 09:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-01-2020 09:49:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0	Initial Entry
Sep-30-2020 10:04:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Toxicity Grade" is missing. Kindly review and update.

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: ILLNESS DETAILS - SEVERE - eCRF Audit Trail History on Sep/29/2020

Form Version: 17-Jul-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Subcategory of Clinical Event:**

Date	Location	User	Value	Reason
Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Was a diagnosis obtained?**

Date	Location	User	Value	Reason
Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Toxicity Grade:**

Date	Location	User	Value	Reason
Oct-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (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 Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-26-2020 14:31:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 09:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-26-2020 09:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital,400 0 Highway 9 East, Little River, SC 29566	Changed Information
Oct-23-2020 16:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	A carriage return (Hitting Enter), leading / trailing spaces or multiple successive spaces (hitting 'Tab key') as it has an important impact. Please delete the entire entry and re-enter the data manually without using copy and pasting
Oct-23-2020 16:17:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	have to reword
Oct-23-2020 14:52:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q R2: A carriage is still identified. Please

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<b>Header Text:</b> c4591001				
<b>Visit:</b> POT_COVID_ILL 1 - Unscheduled Visit on Sep/29/2020		<b>Form:</b> LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History		
<b>Form Version:</b> 15-Sep-2020 21:51		<b>Form Status:</b> Data Complete, Frozen, Verified		
<b>Site No:</b> 1097		<b>Site Name:</b> (1097) Main Street Physician's Care - Waterway		
<b>Subject No:</b> 10971011		<b>Subject Initials:</b> ---		
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 10:39		
		(b) (4), (b) (6)		delete the entire entry and re-enter the data manually without using copy and pasting. Thank you.
Oct-23-2020 08:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 08:17:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 4000 Highway 9 E, Little River , SC 29566	Transcription Error
Oct-23-2020 03:21:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q R2: A carriage is still identified. Please delete the entire entry and re-enter the data manually without using copy and pasting. Thank you.
Oct-22-2020 14:22:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	McLeod Seacoast Hospital 4000 Hwy 9 East Little River SC 29566
Oct-22-2020 13:53:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q R1: A carriage is identified. Please deleting the entire entry and re-entering the data manually(without using copy and paste. Thank you.
Oct-21-2020 22:39:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 4000 Hwy 9 E Little River SC 29566	Transcription Error
Oct-21-2020 22:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-21-2020 22:37:25	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error

<b>Header Text:</b> c4591001				
<b>Visit:</b> POT_COVID_ILL 1 - Unscheduled Visit on Sep/29/2020		<b>Form:</b> LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History		
<b>Form Version:</b> 15-Sep-2020 21:51		<b>Form Status:</b> Data Complete, Frozen, Verified		
<b>Site No:</b> 1097		<b>Site Name:</b> (1097) Main Street Physician's Care - Waterway		
<b>Subject No:</b> 10971011		<b>Subject Initials:</b> ---		
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 10:39		
(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	McLeod Seacoast Medical Center Hospital 4000 Hwy 9 E Little River SC 29566	
Oct-21-2020 14:43:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (b) (4)	Query 1: Opened	A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Medical Center Hospital 4000 Hwy 9 E Little River SC 29566	Initial Entry
<b>3. Collection Date:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/20/2020	Initial Entry
<b>4. Specimen Type:</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry
<b>5.a</b>				
<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 329 <b>Identifier:</b> Test:: C Reactive Protein_PX329 <b>Result::</b>	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			Not Done:: NOT DONE	
			Lab Normal Range:	

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: 28 Not Done:: Lab Normal Range: Unit U/L	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:24:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 10:42:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 28	Initial Entry
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5.b LNMT

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unit U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: Test:: Aspartate Aminotransferase_PX28 Result:: 30 Not Done:: Lab Normal Range: Unit U/L	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aspartate Aminotransferase_PX 28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:24:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	NO.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 10:42:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 30	Initial Entry
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5.c LNMT

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unit U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Define 35 d Identifier: Test:: Alkaline Phosph atase_PX35 Result:: 102 Not Done:: Lab Normal Range: Unit U/L	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:23:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 10:42:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 102	Initial Entry
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5.d LNMT

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unit U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: Test:: Bilirubin_P X21 Result:: 1.5 Not Done:: Lab Normal Range: Unit mg/dL	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:24:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	no.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 10:43:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.5	Initial Entry
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5.e LNMT

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unit mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 47 <b>Identifier:</b> Test:: Blood Urea Nitrogen_PX47 <b>Result::</b> Not Done:: NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Blood Urea Nitrogen_PX47	Initial Entry

5.f Not Done:

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT DONE	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48 Result:: 1.23 Not Done:: Lab Normal Range: Unit mg/dL	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

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**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 48	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Creatinine_PX48	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:23:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 10:43:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

				Please correct or confirm.
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.23	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Oct-09-2020 10:41:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> mg/dL	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/29/2020

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

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

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

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Date	Location	User	Value	Reason
Nov-09-2020 13:29:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	entered in error.
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

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

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Nov-02-2020 09:38:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	not applicable.
Oct-16-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMISTRY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Nov-03-2020 10:01:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-02-2020 19:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-02-2020 19:56:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Nov-02-2020 17:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-02-2020 16:59:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	not applicable duplicate
Oct-27-2020 10:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per database update.
Oct-26-2020 09:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-26-2020 09:41:52 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 400	Changed Information

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Incomplete, Data Complete, Deleted, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

Time (US & Canada)			0 Highway 9 E, Little River, S C 29566	
Oct-23-2020 16:15:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	A carriage return (Hitting Enter), leading / trailing spaces or multiple successive spaces (hitting 'Tab key') as it has an important impact. Please delete the entire entry and re-enter the data manually without using copy and pasting
Oct-23-2020 16:10:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	need to re-word query
Oct-23-2020 14:53:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	A carriage is still identified. Please delete the entire entry and re-enter the data manually without using copy and pasting. Thank you.
Oct-23-2020 08:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 08:18:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 4000 Highway 9 E, Little River , SC 29566	Transcription Error
Oct-23-2020 03:23:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q R2: A carriage is still identified. Please delete the entire entry and re-enter the data manually without using copy and pasting. Thank you.

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Incomplete, Data Complete, Deleted, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

Oct-22-2020 14:25:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-22-2020 14:25:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 4000 Highway 9 East Little River SC 29566	Changed Information
Oct-22-2020 13:57:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q R1: A carriage is still identified. Please delete the entire entry and re-enter the data manually(without using copy and paste). Thank you.
Oct-21-2020 22:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-21-2020 22:38:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 4000 Highway 9 E Little River SC 29566	Transcription Error
Oct-21-2020 14:43:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (b) (4)	Query 1: Opened	A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Oct-16-2020 10:47:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 400 Highway 9 East Little River SC 29566	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Incomplete, Data Complete, Deleted, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

Nov-04-2020 14:07:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Nov-04-2020 10:07:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	has been done again. not sure why keeps quering.
Nov-03-2020 16:48:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Query 1: Reissued:Opened	Please click the "Eraser" icon present on the right side and then consider to apply form level comment with "Not Applicable" in "Reason incomplete".
Nov-03-2020 10:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	Form level comment says not applicable.
Nov-03-2020 10:03:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Initial Entry
Nov-03-2020 10:02:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-03-2020 10:02:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Initial Entry
Nov-03-2020 03:49:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Reissued:Opened	DM2: Please select and remove the response by clicking the "Eraser" icon present on the right side and then consider to apply form level comment with "Not Applicable" in "Reason incomplete". Refer

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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				to section 4.10 of completion guidelines. Thank you.
Nov-02-2020 20:01:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	I am not able to do as you ask.
Nov-02-2020 20:00:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Nov-02-2020 14:09:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q: Thank you for your response however the duplicate row has not been removed. Please remove the row and add form level comment as NOT APPLICABLE after removing the data.
Nov-02-2020 09:38:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	not applicable.
Nov-02-2020 09:38:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	not applicable.
Nov-02-2020 07:10:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	The lab test and test results performed on 20Sep2020 seems to be duplicate. Hence, please check and remove the duplicate entries and add form level comment as NOT APPLICABLE after removing the data. Else clarify.

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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Oct-16-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/20/2020	Initial Entry
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4. Specimen Type:

Date	Location	User	Value	Reason
Nov-02-2020 09:38:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	not applicable.
Oct-16-2020 10:19:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined 329 Identifier: Test:: C Reactive Prot ein_PX329 Result: Not Done:: NOT DONE Lab Normal Ran ge:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> C Reactive Protein_PX329	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

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5.a Not Done:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-02-2020 16:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	duplicate not applicable
Nov-02-2020 16:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> Unit U/L	duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 30 <b>Test::</b> Alanine Aminotransferase_PX30 <b>Result::</b> 28 <b>Not Done::</b> <b>Lab Normal Range:</b> Unit U/L	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-02-2020 16:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-02-2020 16:53:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	duplicate not applicable
Oct-21-2020 06:23:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 22:37:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Information not available!
Oct-18-2020 08:50:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. However, Result is present, but lab normal range (Low, high or Unit) is missing. Please update.
Oct-16-2020 10:21:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference range information is not

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

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Time (US & Canada)				available on the lab report
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 28	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-02-2020 16:54:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unit U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-02-2020 16:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <u>Sponsor-Defined Identifier:</u> <u>Test::</u> Aspartate Aminotransferase_PX28 <u>Result::</u> <u>Not Done::</u> <u>Lab Normal Range:</u>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <u>Sponsor-Defined Identifier:</u> 28 <u>Test::</u> Aspartate Aminotransferase_PX28	Initial Entry

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

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**Generated Time (GMT):** 29-Mar-2021 10:39

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			<b>Result::</b> 30	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Unit</i> U/L	

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Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-02-2020 16:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Aspartate Aminotransferase_PX 28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-02-2020 16:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Duplicate not applicable
Oct-21-2020 06:23:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 22:36:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Information not available!!
Oct-18-2020 08:51:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. However, Result is present, but lab normal range (Low, high or Unit) is missing. Please update.
Oct-16-2020 10:21:16 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference range information is not

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Generated By: (b) (4)

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Time (US & Canada)				available on the lab report
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 30	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-02-2020 16:55:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unit U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-02-2020 16:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Alkaline Phosphatase_PX35 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> 35 <b>Test::</b> Alkaline Phosphatase_PX35	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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			<b>Result::</b> 102	
			<b>Not Done::</b>	
			<b>Lab Normal Range:</b> <i>Unit</i>	
			U/L	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-02-2020 16:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-02-2020 16:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	duplicate not applicable
Oct-21-2020 06:23:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 22:37:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Information not available!
Oct-18-2020 08:51:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. However, Result is present, but lab normal range (Low, high or Unit) is missing. Please update.
Oct-16-2020 10:21:32 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference range information is not

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

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Time (US & Canada)				available on the lab report
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 102	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-02-2020 16:56:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unit U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-02-2020 16:56:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Identifier: Test:: Bilirubin_P X21 Result:: Not Done:: Lab Normal Range:	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> Sponsor-Defined Identifier: 21 Test:: Bilirubin_P X21 Result:: 1.5	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/29/2020

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**Not Done::**

**Lab Normal Range:** *Unit*  
mg/dL

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-02-2020 16:56:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-02-2020 16:56:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Duplicate not applicable
Oct-21-2020 06:23:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 22:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	information not available!
Oct-18-2020 08:52:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. However, Result is present, but lab normal range (Low, high or Unit) is missing. Please update.

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



Header Text: c4591001

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Form Version: 10-Oct-2020 15:58

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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

Oct-16-2020 10:21:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference range information is not available on the lab report
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.5	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-02-2020 16:56:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unit mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-02-2020 16:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Blood Urea Nitr ogen_PX47 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Ra nge:</b>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Define d Identifier:</b> 47	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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

			<b>Test::</b>	Blood Urea Nitrogen_PX47	
			<b>Result::</b>	15	
			<b>Not Done::</b>		
			<b>Lab Normal Range:</b>	<i>Unit</i>	
				mg/dL	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-02-2020 16:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-02-2020 16:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Duplicate not applicable
Oct-21-2020 06:23:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 22:38:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Information not available!
Oct-18-2020 08:52:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. However, Result is present, but lab normal range (Low, high or Unit) is missing. Please update.
Oct-16-2020 10:21:59 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference range information is not

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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Time (US & Canada)				available on the lab report
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 15	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-02-2020 16:57:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unit mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-02-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Creatinine_PX48 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> <b>Sponsor-Defined Identifier:</b> 48 <b>Test::</b> Creatinine_PX48 <b>Result::</b> 1.23	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY -  
eCRF Audit Trail History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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			<b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> mg/dL	
--	--	--	--	--

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-02-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-02-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Duplicate not applicable
Oct-21-2020 06:23:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-19-2020 22:39:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Information not available!
Oct-18-2020 08:53:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Thank you for the response. However, Result is present, but lab normal range (Low, high or Unit) is missing. Please update.
Oct-16-2020 10:22:14 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference range information is not

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Incomplete, Data Complete, Deleted, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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

Time (US & Canada)				available on the lab report
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.23	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-02-2020 16:58:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u>	Duplicate not applicable
Oct-16-2020 10:19:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Unit mg/dL	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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

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

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (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 Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Oct-09-2020 11:20:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Oct-27-2020 10:36:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	As per database update.
Oct-26-2020 09:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information
Oct-26-2020 09:29:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 400 0 Highway 9 E, Little River, S C 29566	Changed Information
Oct-23-2020 16:17:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	A carriage return (Hitting Enter), leading / trailing spaces or multiple successive spaces (hitting 'Tab key') as it has an important impact. Please delete the entire entry and re-enter the data manually without using copy and pasting
Oct-23-2020 16:17:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	need to reword
Oct-23-2020 14:52:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	A carriage is still identified. Please delete the entire entry and re-enter the data

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<b>Header Text:</b> c4591001 <b>Visit:</b> POT_COVID_ILL 1 - Unscheduled Visit <b>Form:</b> LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History <b>Form Version:</b> 15-Sep-2020 21:55 <b>Form Status:</b> Data Complete, Frozen <b>Site No:</b> 1097 <b>Site Name:</b> (1097) Main Street Physician's Care - Waterway <b>Subject No:</b> 10971011 <b>Subject Initials:</b> --- <b>Generated By:</b> (b) (4) <b>Generated Time (GMT):</b> 29-Mar-2021 10:39				
				manually without using copy and pasting. Thank you.
Oct-23-2020 08:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-23-2020 08:19:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 4000 Highway 9 E, Little River , SC 29566	Transcription Error
Oct-23-2020 03:22:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q R2: A carriage is still identified. Please delete the entire entry and re-enter the data manually without using copy and pasting. Thank you.
Oct-22-2020 14:25:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Changed Information
Oct-22-2020 14:25:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 4000 Highway 9 East Little River SC 29566	Changed Information
Oct-22-2020 13:54:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM Q R1: A carriage is still identified. Please delete the entire entry and re-enter the data manually(without using copy and paste). Thank you.
Oct-21-2020 22:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-21-2020 22:41:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Hospital 4000 Highway 9 E Little River SC 29566	Transcription Error

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-21-2020 14:44:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (b) (4)	Query 1: Opened	A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> McLeod Seacoast Medical Center Hospital 4000 Highway 9 E Little River SC 29566	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-09-2020 11:20:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/20/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-09-2020 11:20:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-13-2020 10:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined 1 Identifier: Test:: Hemoglobi n_PX1 Result:: 14.9 Not Done:: Lab Normal Ran Unit ge: g/dL	Initial Entry

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<b>Header Text:</b> c4591001 <b>Visit:</b> POT_COVID_ILL 1 - Unscheduled Visit on Sep/29/2020 <b>Form Version:</b> 15-Sep-2020 21:55 <b>Site No:</b> 1097 <b>Subject No:</b> 10971011 <b>Generated By:</b> (b) (4)				
Nov-13-2020 10:03:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> g/dL	Transcription Error
Nov-12-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10^3/uL	ranges not in documentation
Nov-12-2020 12:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1 <b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> g/dl <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10^3/uL	Changed Information
Nov-11-2020 15:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1 <b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> 14 g/dl <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10^3/uL	Changed Information
Nov-11-2020 15:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1	Changed Information

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> 14gld <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10 <sup>3</sup> /uL	
Oct-26-2020 09:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1 <b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> 14.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 1 <b>Test::</b> Hemoglobi n_PX1 <b>Result::</b> 14.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> g/dL	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Nov-13-2020 10:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry
Nov-12-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	ranges not in documentation
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**5.a Test:**

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Nov-15-2020 16:14:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Closed	Response satisfies query
Nov-13-2020 13:53:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Nov-13-2020 10:07:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Added information
Nov-13-2020 10:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-13-2020 10:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Initial Entry
Nov-13-2020 10:06:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 14.9	Initial Entry
Nov-13-2020 01:25:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Reissued:Opened	Clin: Please the Hemoglobin absolute value and the Unit should be "g/dL" instead of "10^3/uL". Please update accordingly
Nov-12-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Closed	Close Auto Query

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Nov-12-2020 12:08:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	ranges not in documentation
Nov-12-2020 12:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-12-2020 12:05:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> g/lld	Changed Information
Nov-12-2020 02:41:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Reissued:Opened	DM: Thank you for the response. Please consider to update the ranges with available unit from the CRF options. Kindly connect with your CRA for any further assistance if needed.
Nov-11-2020 15:12:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Answered	no lab ranges given.
Nov-11-2020 15:11:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 14 g/lld	Changed Information
Nov-11-2020 15:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Nov-11-2020 15:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Changed Information
Nov-11-2020 15:11:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 14gld	Changed Information
Nov-11-2020 14:45:03 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Opened	Clin: Please the Hemoglobin Unit

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<b>Visit:</b> POT_COVID_ILL 1 - Unscheduled Visit on Sep/29/2020		<b>Form:</b> LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History		
<b>Form Version:</b> 15-Sep-2020 21:55		<b>Form Status:</b> Data Complete, Frozen		
<b>Site No:</b> 1097		<b>Site Name:</b> (1097) Main Street Physician's Care - Waterway		
<b>Subject No:</b> 10971011		<b>Subject Initials:</b> ---		
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 10:39		
Time (US & Canada)				should be "g/dL" instead of "10^3/uL". Please update accordingly
Nov-11-2020 13:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 3: Candidate	Clin: Please the Hemoglobin Unit should be "g/dL" instead of "10^3/uL". Please update accordingly
Nov-09-2020 15:28:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Site confirmed ranges not available. No further action needed.
Nov-09-2020 14:50:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	DM: Do not issue query. Following up to confirm action needed.
Nov-09-2020 09:09:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	data not included in hospital records, comment added 10-26-2020
Nov-08-2020 23:21:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM 2: Lab normal ranges are missing. Please update or add an item level comment for provided reason, else clarify.
Nov-08-2020 19:31:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Section is frozen - comment cannot be added
Nov-07-2020 03:16:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thanks for response. Please add an item level comment for provided reason, else clarify.
Oct-27-2020 23:54:43 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Candidate	Awaiting for clarification. Issue



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)				added in tracker.
Oct-26-2020 09:32:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Data is not in subject record
Oct-26-2020 09:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:29:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:20:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 14.9	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
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Header Text: c4591001

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Nov-13-2020 10:03:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> g/dL	Transcription Error
Oct-26-2020 09:31:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10^3/uL	Changed Information
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Id 2</b> <b>entifier:</b> <b>Test::</b> Hematocrit_ PX2 <b>Result::</b> 43.7 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Form Status: Data Complete, Frozen

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Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hematocrit_PX2	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:28:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:21:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing.

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

				Please correct or confirm.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 43.7	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Unit %	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Id 3 entifier: Test:: Erythrocytes _PX3 Result:: 5.16 Not Done:: Lab Normal Range Unit : 10^6/cu m m	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:31:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:21:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

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Header Text: c4591001

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Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

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Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 5.16	Initial Entry
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5.c LNMT

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10 <sup>6</sup> /cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Identifier: 5 Test:: Platelets_P X5 Result:: 105 Not Done:: Lab Normal Range: <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

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Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:31:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:21:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

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Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 105	Initial Entry
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5.d LNMT

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defined Id 7 entifier: Test:: Leukocytes_ PX7 Result:: 10.29 Not Done:: Lab Normal Range: <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

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Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-12-2020 16:30:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	No.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued:Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:21:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

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Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 10.29	Initial Entry
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5.e LNMT

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-26-2020 09:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined 608 <b>Identifier:</b> Test:: Neutrophils_ PX608 <b>Result::</b> 8.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
Oct-14-2020 14:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined 608 <b>Identifier:</b> Test:: Neutrophils_ PX608 <b>Result::</b> 8.9 <b>Not Done::</b> <b>Lab Normal Range:</b>	Changed Information
Oct-14-2020 14:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined 608 <b>Identifier:</b> Test:: Neutrophils_ PX608 <b>Result::</b> 8.9 <b>Not Done::</b>	

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			<b>Lab Normal Range:</b>	
			<i>Unit</i> 10 <sup>3</sup> /uL	
Oct-14-2020 14:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Neutrophils_ PX608 <b>Result::</b> 8.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>High</i> High  <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Oct-14-2020 14:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Neutrophils_ PX608 <b>Result::</b> 8.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10 <sup>9</sup> /L	New Information
Oct-14-2020 10:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Neutrophils_ PX608 <b>Result::</b> 86.7 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10 <sup>9</sup> /L	What is CCG?
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Neutrophils_ PX608 <b>Result::</b> 86.7	Initial Entry

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

			Not Done::	
			Lab Normal Range:	Unit %

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-09-2020 15:28:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Closed	Site confirmed ranges not available. No further action needed.
Nov-09-2020 14:50:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Reissued:Candidate	DM: Do not issue query. Following up to confirm action needed.

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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5.f Result:

Date	Location	User	Value	Reason
Nov-09-2020 09:10:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Answered	Data not available in hospital records,
Nov-08-2020 23:22:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Reopened	DM 2: The form is unfrozen now. Lab normal ranges are missing. Please update or add an item level comment for provided reason, else clarify.
Nov-08-2020 19:31:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Answered	Section is frozen - comment cannot be added
Nov-07-2020 03:16:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Reopened	DM1: Thanks for response. Please add an item level comment for provided reason, else clarify.
Oct-27-2020 23:55:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Reopened	Awaiting for clarification. Issue added in tracker.
Oct-26-2020 22:37:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 8: Closed	Response satisfies query

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Canada)				
Oct-26-2020 22:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 6: Clo sed	Response satisfies query
Oct-26-2020 09:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Ans wered	Original value is correct
Oct-26-2020 09:33:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 9: Ans wered	Data is not in subject record
Oct-26-2020 09:33:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Ans wered	Data is not in subject record
Oct-26-2020 09:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 9: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-24-2020 01:35:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 8: Ope ned	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-24-2020 01:34:48 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 7: Clo sed	Response satisfies query

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)				
Oct-24-2020 01:32:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 7: Opened	Clin: Please provide the lab normal ranges. The Unit should be << 10^3/uL >>. Please update as appropriate
Oct-23-2020 16:03:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Erica Weaver (b) (4)	Query 6: Opened	What is the unit for the hematology tests where unit is missing?
Oct-15-2020 07:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Closed	Response satisfies query
Oct-15-2020 07:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-14-2020 22:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-14-2020 15:00:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Lab normal range is not available
Oct-14-2020 14:55:43 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Result is present, but lab normal range (Low, high or Unit) is

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Eastern Time (US & Canada)				missing. Please correct or confirm.
Oct-14-2020 14:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Clo sed	Close Auto Query
Oct-14-2020 14:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-14-2020 14:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> 8.9	New Information
Oct-14-2020 10:06:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Ans wered	We do not have that information. What is CCG?
Oct-14-2020 10:05:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Ans wered	We do not have that information
Oct-14-2020 10:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-13-2020 04:38:36	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Reis	DM: Per CCG 8.36.4 Neutrophils,



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Generated By: (b) (4)

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(UTC-05:00) Eastern Time (US & Canada)			sued:O pened	Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10^9/L as units. Please review and update appropriately. Thank you.
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Oct-12-2020 16:30:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	No.
Oct-12-2020 16:25:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	no
Oct-12-2020 05:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Ope ned	DMW4937035;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Re sued:O pened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify.

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Site No: 1097

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Generated By: (b) (4)

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				Thank you.
Oct-09-2020 11:22:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 86.7	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-26-2020 09:32:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Unit</i> 10^3/uL	Initial Entry
Oct-14-2020 14:55:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-14-2020 14:43:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>  <i>Unit</i> 10^3/uL	
Oct-14-2020 14:39:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>High</i> High  <i>Unit</i> 10^3/uL	Changed Information

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-14-2020 10:04:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10^9/L	What is CCG?
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> %	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 609</b> <b>dentifier:</b> <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 0 <b>Not Done::</b> <b>Lab Normal Rang</b> <i>Unit</i> <b>e:</b> 10^3/uL	Initial Entry
Oct-14-2020 14:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 609</b> <b>dentifier:</b> <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 0 <b>Not Done::</b> <b>Lab Normal Rang</b> <b>e:</b>	Changed Information
Oct-14-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 609</b> <b>dentifier:</b> <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 0 <b>Not Done::</b> <b>Lab Normal Rang</b> <i>Unit</i> <b>e:</b> 10^3/uL	Changed Information
Oct-14-2020 14:49:40 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I 609</b>	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Time (US & Canada)		(b) (4), (b) (6)	<b>identifier:</b> <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Rang Unit</b> <b>e:</b> 10^3/uL	
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 609 <b>identifier:</b> <b>Test::</b> Eosinophils_ PX609 <b>Result::</b> 0.3 <b>Not Done::</b> <b>Lab Normal Rang Unit</b> <b>e:</b> %	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-09-2020 15:28:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Site confirmed ranges not available. No further action needed.
Nov-09-2020 14:51:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Candidate	DM: Do not issue query. Following up to confirm action needed.

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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**5.g Result:**

Date	Location	User	Value	Reason
Nov-09-2020 09:12:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Data not available in hospital records.
Nov-08-2020 23:23:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued: Opened	DM 2: The form is unfrozen now. Lab normal ranges are missing. Please update or add an item level comment for provided reason, else clarify.
Nov-08-2020 19:31:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Section is frozen - comment cannot be added
Nov-07-2020 03:16:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued: Opened	DM1: Thanks for response. Please add an item level comment for provided reason, else clarify.
Oct-27-2020 23:56:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued: Candidate	Issue added in tracker. Awaiting for clarification.
Oct-26-2020 22:37:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Closed	Response satisfies query

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

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Generated Time (GMT): 29-Mar-2021 10:39

Canada)				
Oct-26-2020 09:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Ans wered	Original value is correct
Oct-26-2020 09:37:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Ans wered	Data is not in subject record
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-24-2020 01:33:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Ope ned	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-15-2020 07:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Clo sed	Response satisfies query
Oct-14-2020 22:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Clo sed	Auto closed by Validation Check: VC_LB001_08
Oct-14-2020 15:00:55 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans wered	Lab normal range is not available.

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Generated Time (GMT): 29-Mar-2021 10:39

(US & Canada)				
Oct-14-2020 14:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-14-2020 14:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-14-2020 14:51:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0	Changed Information
Oct-14-2020 14:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-14-2020 10:06:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	What is CCG?
Oct-13-2020 04:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	DM: Per CCG 8.36.4 Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 <sup>9</sup> /L as units. Please review and update appropriately.

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Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

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Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

				Thank you.
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Clo sed	Response satisfies query
Oct-12-2020 16:29:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Ans wered	No.
Oct-12-2020 16:26:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 2: Ans wered	No.
Oct-12-2020 05:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [Redacted]	Query 2: Ope ned	DMW4937034;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4) [Redacted]	Query 1: Reis sued:O pened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:22:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Query 1: Ans wered	Labs are in dictation there is no lab report that contains that information.

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

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Generated Time (GMT): 29-Mar-2021 10:39

Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0.3	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
Oct-14-2020 14:56:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-14-2020 14:49:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> %	Initial Entry

5.h

Date	Location	User	Value	Reason
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined Identifier: Test:: Monocytes_PX612 Result:: 0.7 Not Done:: Lab Normal Range: <i>Unit</i> e: 10 <sup>3</sup> /uL	Initial Entry

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on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology -  
eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-14-2020 14:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 612 <b>dentifier:</b> <b>Test::</b> Monocytes_ PX612 <b>Result::</b> 0.7 <b>Not Done::</b> <b>Lab Normal Rang</b> <b>e:</b>	Changed Information
Oct-14-2020 14:52:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 612 <b>dentifier:</b> <b>Test::</b> Monocytes_ PX612 <b>Result::</b> 0.7 <b>Not Done::</b> <b>Lab Normal Rang</b> <i>Unit</i> <b>e:</b> 10 <sup>3</sup> /uL	Changed Information
Oct-14-2020 14:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 612 <b>dentifier:</b> <b>Test::</b> Monocytes_ PX612 <b>Result::</b> 6.6 <b>Not Done::</b> <b>Lab Normal Rang</b> <i>Unit</i> <b>e:</b> 10 <sup>3</sup> /uL	Changed Information
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined I</b> 612 <b>dentifier:</b> <b>Test::</b> Monocytes_P X612 <b>Result::</b> 6.6 <b>Not Done::</b> <b>Lab Normal Rang</b> <i>Unit</i> <b>e:</b> %	Initial Entry

Header Text: c4591001

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Generated By: (b) (4)

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5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-09-2020 15:27:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Site confirmed ranges not available. No further action needed.
Nov-09-2020 14:51:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Candidate	DM: Do not issue query. Following up to confirm action needed.
Nov-09-2020 09:13:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Data not available in hospital records.
Nov-08-2020 23:22:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	DM 2: The form is unfrozen now. Lab normal ranges are missing. Please update or add an item level comment for provided reason, else clarify.
Nov-08-2020 19:31:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Section is frozen - comment cannot be added
Nov-07-2020 03:16:52	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Opened	DM1: Thanks for

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<b>Header Text:</b> c4591001				
<b>Visit:</b> POT_COVID_ILL 1 - Unscheduled Visit on Sep/29/2020		<b>Form:</b> LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History		
<b>Form Version:</b> 15-Sep-2020 21:55		<b>Form Status:</b> Data Complete, Frozen		
<b>Site No:</b> 1097		<b>Site Name:</b> (1097) Main Street Physician's Care - Waterway		
<b>Subject No:</b> 10971011		<b>Subject Initials:</b> ---		
<b>Generated By:</b> (b) (4)		<b>Generated Time (GMT):</b> 29-Mar-2021 10:39		
(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		response. Please add an item level comment for provided reason, else clarify.
Oct-27-2020 23:57:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Reissued:Candidate	Issue added in tracker. Awaiting for clarification.
Oct-26-2020 22:37:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Closed	Response satisfies query
Oct-26-2020 09:37:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Data is not in subject record
Oct-26-2020 09:37:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Original value is correct
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-24-2020 01:33:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Opened	Clin: The Unit should be << 10^3/uL >>. Please update accordingly

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5.h Result:

Date	Location	User	Value	Reason
Oct-15-2020 07:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-14-2020 22:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-14-2020 15:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Lab normal range is not available
Oct-14-2020 14:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-14-2020 14:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-14-2020 14:52:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 0.7	Changed Information

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Site Name: (1097) Main Street Physician's Care - Waterway

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Oct-14-2020 14:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-14-2020 10:07:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	What is CCG?
Oct-13-2020 04:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reis sued:O pened	DM: Per CCG 8.36.4 Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10^9/L as units. Please review and update appropriately. Thank you.
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clos ed	Response satisfies query
Oct-12-2020 16:27:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Ans wered	No.
Oct-12-2020 16:25:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	No

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-12-2020 05:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW4937033;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued: Opened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:22:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 6.6	Initial Entry

**5.h LNMT**

Date	Location	User	Value	Reason
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry



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Site Name: (1097) Main Street Physician's Care - Waterway

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Generated By: (b) (4)

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Oct-14-2020 14:56:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-14-2020 14:51:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10^3/uL	Changed Information
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> %	Initial Entry

5.i

Date	Location	User	Value	Reason
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I 610 identifier: Test:: Basophils_P X610 Result:: 0 Not Done:: Lab Normal Rang <i>Unit</i> e: 10^3/uL	Initial Entry
Oct-14-2020 14:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I 610 identifier: Test:: Basophils_P X610 Result:: 0 Not Done:: Lab Normal Range :	Changed Information
Oct-14-2020 14:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Defined I 610 identifier: Test:: Basophils_P X610 Result:: 0 Not Done::	Changed Information

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Lab Normal Range:</b> <i>Unit</i> e: 10 <sup>3</sup> /uL	
Oct-14-2020 14:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2% Normal Range <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> e: 10 <sup>3</sup> /uL	Changed Information
Oct-13-2020 16:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2% Normal Range <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> e: %	New Information
Oct-13-2020 16:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2% <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> e: %	Value entered exactly as it appears on medical records. I do not know how to convert.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 610 <b>Test::</b> Basophils_P X610 <b>Result::</b> 0.2 <b>Not Done::</b>	Initial Entry

**Header Text:** c4591001

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**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

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**Subject Initials:** ---

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

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			<b>Lab Normal Range</b>	<b>Unit</b>	
			<b>e:</b>	<b>%</b>	

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Header Text: c4591001

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Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

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Generated By: (b) (4)

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-09-2020 15:27:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Closed	Site confirmed ranges not available. No further action needed.
Nov-09-2020 14:51:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Reissued:Candidate	DM: Do not issue query. Following up to confirm action needed.
Nov-09-2020 09:14:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Answered	data not available in hospital records.
Nov-08-2020 23:21:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Reissued:Opened	DM 2: The form is unfrozen now. Lab normal ranges are missing. Please update or add an item level comment for provided reason, else clarify.
Nov-08-2020 19:31:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Answered	Section is frozen - comment cannot be added
Nov-07-2020 03:16:26	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Reissued:Opened	DM: Thanks for

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		response. Please add an item level comment for provided reason, else clarify.
Oct-27-2020 23:57:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Reissued:Candidate	Issue added in tracker. Awaiting for clarification.
Oct-26-2020 22:36:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 7: Closed	Response satisfies query
Oct-26-2020 09:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 8: Answered	Data is not in subject record
Oct-26-2020 09:38:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 7: Answered	Original value is correct
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 8: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-24-2020 01:34:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4), (b) (6)	Query 7: Opened	Clin: The Unit should be << 10 <sup>3</sup> /uL >>. Please update accordingly
Oct-15-2020 07:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Closed	Response satisfies query
Oct-15-2020 07:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-15-2020 07:56:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-14-2020 15:01:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Lab normal range is not available.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-14-2020 14:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-14-2020 14:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Closed	Close Auto Query
Oct-14-2020 14:53:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 0	Changed Information
Oct-14-2020 14:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 5: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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5.i Result:

Date	Location	User	Value	Reason
Oct-14-2020 10:10:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	We do not have that information.
Oct-14-2020 10:09:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	The lab report is 0.2%
Oct-14-2020 03:16:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 4: Opened	Lab Result is not valid and should be a numeric value. Please review and update as necessary based on the Reference Range provided in the Lab Records (please ensure no commas or ranges). (b) (4)
Oct-13-2020 22:14:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-13-2020 16:30:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : 0.2% Normal Range	New Information
Oct-13-2020	ACV0PFEINFP6000	auto query	Query	Result is present, but

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)



**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

16:27:00 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)	3: Op ened	lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-13-2020 16:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: An swere d	Value entered exactly as it appears on medical records. I do not know how to convert.
Oct-13-2020 16:27:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry</b> : 0.2%	Value entered exactly as it appears on medical records. I do not know how to convert.
Oct-13-2020 04:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Rei ssued: Opene d	DM: Per CCG 8.36.4 Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10 <sup>9</sup> /L as units. Please review and update appropriately. Thank you.
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Clo sed	Response satisfies query
Oct-12-2020 16:28:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: An swere d	No.
Oct-12-2020 16:27:11	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: An	No.



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

(UTC-05:00) Eastern Time (US & Canada)			swere d	
Oct-12-2020 05:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Op ened	DMW4937036;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Rei ssued: Opene d	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:22:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: An swere d	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Op ened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry</b> : 0.2	Initial Entry

**5.i LNMT**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
Oct-14-2020 14:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Changed Information
Oct-14-2020 14:52:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Changed Information
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes _PX611 <b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
Oct-14-2020 14:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes _PX611 <b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Range:</b>	New Information
Oct-14-2020 14:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes _PX611	Changed Information

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

			<b>Result::</b> 0.6 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> %	
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 611 <b>Test::</b> Lymphocytes _PX611 <b>Result::</b> 5.9 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Unit</i> %	Initial Entry

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-26-2020 22:36:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 6: Closed	Response satisfies query
Oct-26-2020 22:36:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Closed	Response satisfies query
Oct-26-2020 09:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 5: Answered	Original value is correct
Oct-26-2020 09:34:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 6: Answered	Data is not in subject record

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 6: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-24-2020 01:34:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4)	Query 5: Ope ned	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-15-2020 07:59:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Clos ed	Response satisfies query
Oct-14-2020 22:02:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Clos ed	Auto closed by Validation Check: VC_LB001_08
Oct-14-2020 15:02:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Ans wered	Lab normal range is not available.
Oct-14-2020 14:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 4: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-14-2020 14:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Clos ed	Close Auto Query

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-14-2020 14:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-14-2020 14:54:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data E ntry:</b> 0.6	Changed Information
Oct-14-2020 10:10:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Ans wered	What is CCG?
Oct-13-2020 04:38:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Reis sued:O pened	DM: Per CCG 8.36.4 Neutrophils, Eosinophils, Monocytes, Basophils and Lymphocytes should be entered as absolute values using 10^9/L as units. Please review and update appropriately. Thank you.
Oct-13-2020 04:35:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Clos ed	Response satisfies query
Oct-12-2020 16:29:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Ans wered	No.

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:55**Form Status:** Data Complete, Frozen**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39

Oct-12-2020 16:26:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Ans wered	No
Oct-12-2020 05:06:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4) [REDACTED]	Query 2: Ope ned	DMW4937032;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-10-2020 02:48:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4) [REDACTED]	Query 1: Reis sued:O pened	Kindly verify and confirm if there are any low, high ranges available if yes update ranges under LNMT, Lab Normal Range. Else clarify. Thank you.
Oct-09-2020 11:23:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Ans wered	Labs are in dictation there is no lab report that contains that information.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Ope ned	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data E ntry:</b> 5.9	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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*5.j LNMT*

Date	Location	User	Value	Reason
Oct-26-2020 09:34:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> <i>Unit</i> 10 <sup>3</sup> /uL	Initial Entry
Oct-14-2020 14:55:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b>	New Information
Oct-09-2020 11:19:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> <i>Unit</i> %	Initial Entry



**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - COVID - Audit Trail  
on Sep/29/2020

**Form Version:** 21-Aug-2020 02:50

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/29/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/20/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> 1 <b>Systolic::</b> 17 1 <b>Diastolic::</b> 81 <b>Respiratory Rate in respirati</b> 20 <b>ons/minute:</b> <b>Heart Rate in beats/minute:</b> 99	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a Systolic:**

Date	Location	User	Value	Reason
Sep-30-2020 04:35:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Hx of Hypertension
Sep-29-2020 16:01:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Data is correct as etered.
Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 171 is outside of Normal Range 90 - 140.

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: VITAL SIGNS - COVID - eCRF Audit Trail History on Sep/29/2020

Form Version: 21-Aug-2020 02:50

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 171	Initial Entry
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**2.a Diastolic:**

Date	Location	User	Value	Reason
Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 81	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 20	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Sep-29-2020 15:59:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail on Sep/29/2020

**Form Version:** 21-Aug-2020 02:51

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Sep-29-2020 16:02:21 (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 Sep/29/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History

Form Version: 21-Aug-2020 02:51

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 16:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/20/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 16:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Record Identifier:: 1 Oxygen Saturation: 97.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 16:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
Sep-29-2020 16:02:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.0	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: OXYGENATION PARAMETERS - eCRF Audit Trail History on Sep/29/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Oct-09-2020 11:23:23 (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
Oct-09-2020 11:23:23 (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
Oct-09-2020 11:23:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit  
on Sep/29/2020**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF  
Audit Trail History**Form Version:** 06-Jul-2020 21:55**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Oct-09-2020 11:29:53 (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
Oct-09-2020 11:29:53 (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
Oct-09-2020 11:29:53 (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
Oct-09-2020 11:29:53 (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
Oct-09-2020 11:29:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Ongoing?**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 - Unscheduled Visit on Sep/29/2020

**Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS - eCRF Audit Trail History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Oct-09-2020 11:29:53 (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    **Form:** IMAGING - Audit Trail  
on Sep/29/2020

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

**Form Status:**

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Sep-29-2020 16:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 - Unscheduled Visit Form: IMAGING - eCRF Audit Trail History on Sep/29/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Sep-29-2020 16:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/20/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Sep-29-2020 16:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Sep-29-2020 16:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> X-RAY	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
Sep-29-2020 16:04:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  Left upper Lobe pneumonia,	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/29/2020

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit  
Trail History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date of Visit**

Date	Location	User	Value	Reason
Oct-30-2020 08:32:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/29/2020	Initial Entry

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

Date	Location	User	Value	Reason
Oct-30-2020 08:32:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/29/2020**Form Version:** 22-Apr-2020 21:03**Site No:** 1097**Subject No:** 10971011**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Oct-30-2020 08:32:47 (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-30-2020 08:32:47 (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
Oct-30-2020 08:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-30-2020 08:32:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-30-2020 08:32:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection:  Oct/29/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Oct-30-2020 08:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID: BPVCMC	Initial Entry

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/29/2020**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -  
eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1097**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject No:** 10971011**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 10:39**5.a Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 08:33:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVCMC	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Oct-30-2020 08:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVCMD	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 08:34:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVCMD	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Oct-30-2020 08:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BPVCMF	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 08:34:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BPVCMF	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Oct-30-2020 08:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BL9XGJ	Initial Entry

Header Text: c4591001

Visit: POT\_COVID\_CONVA 1 - Unscheduled  
Visit on Oct/29/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

**5.d Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 08:58:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9XGJ	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Oct-30-2020 08:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sample ID: BL9XGK	Initial Entry

**5.e Sample ID**

Date	Location	User	Value	Reason
Oct-30-2020 08:59:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BL9XGK	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (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: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Oct-15-2020 14:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/9/2020	Changed Information
Oct-14-2020 14:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Oct/5/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Oct-14-2020 14:31:19 (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-14-2020 15:43:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-14-2020 14:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-14-2020 14:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry
Oct-14-2020 14:18:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please complete the End of Treatment CRF. Per Guidelines, If the Participant receives all vaccinations as per protocol and completes the follow-up visit procedures within

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

				the 1-month post vaccination period, report the status as COMPLETED.
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Sep-22-2020 11:58:14 (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:** 1097

**Subject No:** 10971011

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

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Status:**

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (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: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Category:**

Date	Location	User	Value	Reason
Sep-22-2020 11:58:14 (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
Sep-22-2020 11:58:14 (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
Sep-30-2020 01:59:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-25-2020 14:25:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	The patient has been contacted and cannot come to the clinic until September 29th.
Sep-24-2020 08:13:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Salim Bouguermouh (b) (4), (b) (6)	Query 1: Opened	Clin: Please PNEMONIA symptoms experienced by the subject are listed per protocol as Covid Illness symptoms and should trigger a COVID Illness Visit irrespective of other potential diagnosis and a NASAL SWAB needs to be collected ASAP.
Sep-22-2020 11:58:14 (UTC-05:00) Eastern	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Pneumonia	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Locked, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Time (US & Canada)

4. Start Date Time:

Date	Location	User	Value	Reason
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Sep/20/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Oct-07-2020 12:46:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO End Date Time:  Oct/5/2020 11:00	New Information
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 3	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Sep-22-2020 21:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Pneumonia: Response to "Is the adverse event

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

				serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/in capacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>YES</p>	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
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<p><b>Data Entry:</b> NO</p>	Initial Entry

090177e196ae3eb9\Final\Final On: 01-Apr-2021 04:58 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

Subject Initials: ---

Generated Time (GMT): 29-Mar-2021 10:39

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Sep-23-2020 09:55:54 (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  If Other, specify:  Pt contracted pneumonia from somewhere	Changed Information
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Sep-22-2020 11:58:14 (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
Sep-22-2020 11:58:14 (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
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Oct-09-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen

Site Name: (1097) Main Street Physician's Care - Waterway

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Generated Time (GMT): 29-Mar-2021 10:39

06:59:55 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Oct-08-2020 16:38:28 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Safety data has been updated as of 10-8-2020
Oct-08-2020 06:06:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	SAE RECON:AER#2020365457,outcome was updated to RECOVERED/RESOLVED in AE CRF but retained as UNKNOWN in Safety database. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Oct-07-2020 12:50:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Closed	Close Auto Query
Oct-07-2020 12:50:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Oct-07-2020 12:46:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Opened	For AE Pneumonia: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Sep-24-2020 05:05:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-24-2020 00:31:05 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query

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**Header Text:** c4591001  
**Visit:** Logs - Unscheduled  
**Form Version:** 22-Apr-2020 21:02  
**Site No:** 1097  
**Subject No:** 10971011  
**Generated By:** (b) (4)

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History  
**Form Status:** Data Complete, Locked, Frozen  
**Site Name:** (1097) Main Street Physician's Care - Waterway  
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Eastern Time (US & Canada)				
Sep-23-2020 09:58:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	As far as we know, the event is still ongoing.
Sep-23-2020 09:54:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	For AE Pneumonia: Response to "What was the outcome of this adverse event?" is 'Unknown' but End Date/Time is provided or "Is the adverse event still ongoing?" is marked "Yes".
Sep-23-2020 09:54:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	We had it as unknown in the beginning because we have no information. The query sounded like it should be changed to recovering/resolving so we changed it. Now we are changing it back to 'unknown' because we do not know.
Sep-23-2020 09:54:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNKNOWN	We had it as unknown in the beginning because we have no information. The query sounded like it should be changed to recovering/resolving so we changed it. Now we are changing it back to 'unknown' because we do not know.
Sep-23-2020 05:12:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON:AER#2020365457,outcome was reported as UNKNOWN to Safety DB however, recorded as RECOVERING/RESOLVING on AE CRF. Please confirm correct outcome. If safety update is required, please submit a follow-up form.
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RE SOLVING	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**



**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

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Date	Location	User	Value	Reason
Sep-22-2020 11:58:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Sep-22-2020 21:29:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2020365457	Initial Entry

Header Text: c4591001

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Site No: 1097

Subject No: 10971011

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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**1. Category:**

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (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-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 2	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEAD LACERATION	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Feb-03-2021 13:02:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Closed	Response satisfies query
Feb-03-2021 11:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-03-2021 11:44:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/20/2020 16:08	New Information
Feb-02-2021 12:26:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Svitlana Tonkovyd (b) (4)	Query 1: Opened	GPD Clin: Can you please confirm start date of AE "HEAD LACERATION"- per information on SAE #2020365457 visit to

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

				ER had happened 20.09.2020. Did pnt visit ER twice on 20 and 22 of Sep? Please review and adjust start date, else clarify in query response
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/22/2020 UNK:UNK	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time: Sep/29/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Feb-03-2021 13:21:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-03-2021 11:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-03-2021 11:45:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	New Information
Feb-02-2021 12:05:37 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Please complete this field.

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).

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Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 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-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  ACCIDENT IN ER	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT APPLICABLE	Initial Entry

**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

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Form Status: Data Complete, Frozen

Site No: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

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Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-01-2021 16:38:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**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:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-11-2021 16:12:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**Header Text:** c4591001**Visit:** Potential ReVax Initial Contact -  
Unscheduled**Form Version:** 10-Dec-2020 02:25**Site No:** 1097**Subject No:** 10971011**Generated By:** (b) (4)**Form:** FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail  
History**Form Status:** Data Complete, Frozen**Site Name:** (1097) Main Street Physician's Care - Waterway**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 10:39[Back to Form](#)**1. Select appropriate response - Is participant willing to return for Vaccination 3?**

Date	Location	User	Value	Reason
Feb-12-2021 10:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-12-2021 01:03:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-11-2021 16:19:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-11-2021 16:19:43 (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

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

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

**Site No:** 1097

**Subject No:** 10971011

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

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

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

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Feb-12-2021 10:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/13/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Feb-12-2021 10:19:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILITY FOR A DDITIONAL VACCINATION	Initial Entry



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: 1097

Site Name: (1097) Main Street Physician's Care - Waterway

Subject No: 10971011

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 10:39

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**1. Subject Status**

Date	Location	User	Value	Reason
Oct-14-2020 14:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Aug-25-2020 15:40:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Aug-25-2020 15:33:12 (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
Oct-15-2020 14:30:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/9/2020	Changed Information
Oct-14-2020 14:31:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Oct/5/2020	Initial Entry
Aug-25-2020 15:40:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/20/2020	Initial Entry
Aug-25-2020 15:33:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Aug/20/2020	Initial Entry

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**Header Text:** c4591001

**Visit:** Investigator Signature - Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

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

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

**Site No:** 1097

**Site Name:** (1097) Main Street Physician's Care - Waterway

**Subject No:** 10971011

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 10:39

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**1. Casebook Signature**

Date	Location	User	Value	Reason
Oct-21-2020 22:28:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry