

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Informed Consent**

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/8/2020
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**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** DEMOGRAPHY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Demography**

1.	Subject ID	[11311151]
2.	Birth Date:	(b) (6)/1937
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:	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** DATE OF VISIT

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Sep/8/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** INCLUSION/EXCLUSION CRITERIA

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Subject No:** 11311151

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

**Form:** DISPOSITION - SCREENING

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Disposition - Screening**

1.	Date of Completion/Discontinuation /Death	Sep/8/2020
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:** 1131

**Subject No:** 11311151

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

**Form:** GENERAL MEDICAL HISTORY

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Medical History Details**

1.a	Line/MH Number:	[1]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hearing loss in both ears]
	Start Date:	UNK/UNK/1970
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[hearing device wearer in both ears]
	Start Date:	UNK/UNK/2014
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[myopia]
	Start Date:	UNK/UNK/1953
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

1.d	Line/MH Number:	[4]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[glaucoma]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.e	Line/MH Number:	[5]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[cataract surgery in both eyes]
	Start Date:	UNK/UNK/2016
	Ongoing:	NO End Date: UNK/UNK/2016
1.f	Line/MH Number:	[6]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[chronic dry eye]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

1.g	Line/MH Number:	[7]	
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[allergic rhinitis, seasonal]	
	Start Date:	UNK/UNK/1970	
	Ongoing:	YES	
1.h	Line/MH Number:	[8]	<a href="#">Comments</a>
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[moderate intermittent asthma]	<a href="#">Comments</a>
	Start Date:	UNK/UNK/1985	<a href="#">Comments</a>
	Ongoing:	YES	<a href="#">Comments</a>
1.i	Line/MH Number:	[9]	
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[heart attack]	
	Start Date:	UNK/UNK/1990	
	Ongoing:	NO End Date: UNK/UNK/1990	

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

1.j	Line/MH Number:	[10]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[high blood pressure]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.k	Line/MH Number:	[11]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[edema in both feet]
	Start Date:	UNK/UNK/2016
	Ongoing:	YES
1.l	Line/MH Number:	[12]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[mixed hyperlipdemia]
	Start Date:	UNK/UNK/1990
	Ongoing:	YES
1.m	Line/MH Number:	[13]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[atherosclerosis in both carotid arteries]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

1.n	Line/MH Number:	[14]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[recurrent heartburn]
	Start Date:	UNK/UNK/2018
	Ongoing:	YES
1.o	Line/MH Number:	[15]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[chronic kidney disease, stage 3]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.p	Line/MH Number:	[16]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[urinary incontinence]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES
1.q	Line/MH Number:	[17]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[erectile dysfunction]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

1.r	Line/MH Number:	[18]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[benign prostatic hypertrophy with urinary obstruction]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.s	Line/MH Number:	[19]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[transient ischemic attacks, more than one per subject, but not clear on specific number]
	Start Date:	UNK/UNK/2018
	Ongoing:	NO End Date: UNK/UNK/2018
1.t	Line/MH Number:	[20]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[chronic anemia]
	Start Date:	UNK/UNK/2011
	Ongoing:	YES

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

1.u	Line/MH Number:	[21]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[osteoarthritis in both hands]
	Start Date:	Mar/UNK/2020
	Ongoing:	YES
1.v	Line/MH Number:	[22]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[prostate cancer]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011
1.w	Line/MH Number:	[23]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[tobacco use, past, cigarettes, 0.5 pack per day]
	Start Date:	UNK/UNK/1958
	Ongoing:	NO End Date: UNK/UNK/1964

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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

1.x	Line/MH Number:	[24]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[deviated septum repair]
	Start Date:	UNK/UNK/1970
	Ongoing:	NO End Date: UNK/UNK/1970
1.y	Line/MH Number:	[25]
	Disease/Syndrome /Surgery/Non-Drug Allergies/Drug Allergies:	[prostatectomy]
	Start Date:	UNK/UNK/2011
	Ongoing:	NO End Date: UNK/UNK/2011

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/8/2020
2.	Weight:	[78.0]
3.	Unit:	kg
4.	Height:	[161.4]
5.	Unit:	cm
6.	Body Mass Index:	[29.9]

**Vital Signs Details**

7.a	Record Identifier:	1
	Temperature:	[36.8]
	Unit:	C
	Temperature Location:	ORAL CAVITY

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** RANDOMIZATION

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Disposition**

1.	Randomization Date :	Sep/8/2020
2.	Randomization Number:	[255113]
3.	Randomization Group:	[ ]

**Header Text:** c4591001

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

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/8/2020
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	[BN6DSB]
5.b	Sample ID	[BL9W0M]
5.c	Sample ID	[BL9W0N]

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**Header Text:** c4591001

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

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/8/2020
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	[BN6DZJ]
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** VACCINATION

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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/8/2020 21:17
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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** REACTOGENICITY DIARY

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Reactogenicity Diary**

1.	Select appropriate response - Reactogenicity diary collection	NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT
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**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** DATE OF VISIT

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

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

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Vital Signs**

1.	Date:	Sep/29/2020
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**Vital Signs Details**

2.a	Record Identifier:	1
	Temperature:	[36.7]
	Unit:	C
	Temperature Location:	ORAL CAVITY

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[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	[BP9B2P]
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[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/29/2020 13:38
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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Nov/3/2020
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/3/2020
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	[BS7XBY]
5.b	Sample ID	[BS7XBX]
5.c	Sample ID	[BP99ZF]

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V4\_MONTH6\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form:** DATE OF VISIT

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V5\_MONTH12\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** DATE OF VISIT

**Form Status:** Not Started

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**Date of Visit**

1.	Date of Visit	//
2.	Erroneous Visit	

**Header Text:** c4591001

**Visit:** V6\_MONTH24\_L

**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/16/2020
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Signs and Symptoms**

1.	Date of Assessment:	Dec/16/2020
2.	Date of First Symptom Started:	Dec/16/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Dec/19/2020

**Symptoms**

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.	Not Applicable	Not Applicable	Not Applicable	Not Applicable	Not Applicable	<a href="#">Repeating Pages</a>
2.	Jan/17/2021	SWABBED MATERIAL	NASOPHARYNX	SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2	SARS-COV-2 DIAGNOSTIC TEST	<a href="#">Repeating Pages</a>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Microbiology Specimen**

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Microbiology Specimen

1.	Actual Date of Collection:	Jan/17/2021
2.	Specimen Type:	SWABBED MATERIAL
3.	Specimen Collection Location:	NASOPHARYNX
4.	Assay Code and Description:	SEVERE ACUTE RESP SYNDROME CORONAVIRUS 2
5.	Device Type:	SARS-COV-2 DIAGNOSTIC TEST
6.	Trade Name:	OTHER
7.	Test Result:	NEGATIVE
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[nalt unknown]

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB SELF**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	NO
4.	If no sample was collected or sample was not collected according to protocol, please provide reason:	[waiting on swab from subject]

**Aliquot**

Please enter barcode for each aliquot.

5.	Sample ID	[ ]
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form:** ELECTRONIC SAMPLE TRACKING - NASAL  
SWAB**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

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

**Aliquot**

Please enter barcode for each aliquot.

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Health Care Utilization**

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	NO

**Health Care Utilization Other**

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

**Health Care Utilization**

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

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**Header Text:** c4591001

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

**Form:** HOSPITALIZATION DETAILS

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Dec/17/2020	NO Discharge Date:  Dec/19/2020	<a href="#">Repeating Pages</a>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HOSPITALIZATION DETAILS

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Hospitalization Details**

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Dec/17/2020
4.	Ongoing?	NO Discharge Date: Dec/19/2020

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	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 on Dec/16/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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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>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** ILLNESS DETAILS

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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[eCRF Audit Trail History](#)

**Illness Details**

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 14-Jan-2021 02:30

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
2.	CLINICAL CHEMISTRY	[ ]	Dec/17/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	[ ]	
					30	Alanine Aminotransferase_PX30	[ ]	
					28	Aspartate Aminotransferase_PX28	[ ]	
					35	Alkaline Phosphatase_PX35	[ ]	
					21	Bilirubin_PX21	[ ]	
					47	Blood Urea Nitrogen_PX47	43	
					48	Creatinine_PX48	2.0	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 20-Feb-2021 02:26

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
3.	CLINICAL CHEMISTRY	[ ]	Dec/18/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>
					329	C Reactive Protein_PX329	[ ]	
					30	Alanine Aminotransferase_PX30	[ ]	
					28	Aspartate Aminotransferase_PX28	[ ]	
					35	Alkaline Phosphatase_PX35	[ ]	
					21	Bilirubin_PX21	[ ]	
					47	Blood Urea Nitrogen_PX47	40	
					48	Creatinine_PX48	1.7	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY**Form Version:** 21-Aug-2020 02:49**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Lab Chemistry Details**

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

**Lab Result**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	Dec/17/2020
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

**Header Text:** c4591001

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[43]
	Not Done:	
	LNMT	Low [7] High [25] Unit mg/L
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[2.0]
	Not Done:	
	LNMT	Low [0.7] High [1.3] Unit mg/dL

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	Dec/18/2020
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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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

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5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[40]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[1.7]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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**Header Text:** c4591001

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING  
Hematology

Form Version: 14-Jan-2021 02:24

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
2.	HEMATOLOGY	[ ]	Dec/17/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>
					1	Hemoglobin_PX1	12.5	
					2	Hematocrit_PX2	36.9	
					3	Erythrocytes_PX3	[ ]	
					5	Platelets_PX5	129	
					7	Leukocytes_PX7	6.4	
					608	Neutrophils_PX608	68.2	
					609	Eosinophils_PX609	[ ]	
					612	Monocytes_PX612	[ ]	
					610	Basophils_PX610	[ ]	
					611	Lymphocytes_PX6	[ ]	

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**Header Text:** c4591001

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

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

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
						11		

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Header Text: c4591001

Visit: POT\_COVID\_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING  
Hematology

Form Version: 20-Feb-2021 02:18

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
3.	HEMATOLOGY	[ ]	Dec/18/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	<a href="#">Repeating Pages</a>
					1	Hemoglobin_PX1	11.1	
					2	Hematocrit_PX2	32.6	
					3	Erythrocytes_PX3	[ ]	
					5	Platelets_PX5	108	
					7	Leukocytes_PX7	[ ]	
					608	Neutrophils_PX608	[ ]	
					609	Eosinophils_PX609	[ ]	
					612	Monocytes_PX612	[ ]	
					610	Basophils_PX610	[ ]	
					611	Lymphocytes_PX6	[ ]	

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
						11		

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Unscheduled Visit on Dec/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)[Form Comments](#)[eCRF Audit Trail History](#)**Laboratory Data Hematology**

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

**Lab Result**

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

**Header Text:** c4591001

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

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

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

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

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

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

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

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

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**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	Dec/17/2020
4.	Specimen Type:	BLOOD

### Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[12.5]
	Not Done:	
	LNMT	Low [13.1] High [17.6] Unit /uL

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[36.9]
	Not Done:	
	LNMT	Low [39] High [51.5] Unit %
5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[129]
	Not Done:	
	LNMT	Low [154] High [393] Unit /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[6.4]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[68.2]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology**Form Version:** 20-Feb-2021 02:18**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)[eCRF Audit Trail History](#)[Form Audit Trail](#)**Laboratory Data Hematology**

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[ ]
3.	Collection Date:	Dec/18/2020
4.	Specimen Type:	BLOOD

**Lab Result**

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[11.1]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[32.6]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[108]
	Not Done:	
	LNMT	Low [ ] High [ ] Unit
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

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**Site No:** 1131

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**Subject No:** 11311151

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

**Generated Time (GMT):** 29-Mar-2021 11:34

5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit
5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[ ]
	Not Done:	NOT DONE
	LNMT	Low [ ] High [ ] Unit

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details			Form Instance
1.	Dec/17/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		Not Applicable	224	70	

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 14-Jan-2021 02:17

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details			Form Instance
2. DELETED	Dec/18/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	136	58	

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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - COVID

**Form Version:** 20-Feb-2021 02:11

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details			Form Instance
3.	Dec/18/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	180	66	
4.	Dec/19/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	168	71	
5. DELETED	Dec/17/2020	<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>
		1	186	53	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

1.	Date:	Dec/17/2020	<a href="#">Comments</a>
----	-------	-------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	1	
	Systolic:	[224]	<a href="#">Comments</a>
	Diastolic:	[70]	<a href="#">Comments</a>
	Respiratory Rate in respirations/minute:	[18]	<a href="#">Comments</a>
	Heart Rate in beats/minute:	[40]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 14-Jan-2021 02:17

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Vital Signs

1.	Date:	Dec/18/2020
----	-------	-------------

### Vital Signs Details

2-a	Record Identifier:	4
	Systolic:	[136]
	Diastolic:	[58]
	Respiratory Rate in respirations/minute:	[46]
	Heart Rate in beats/minute:	[36]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

1.	Date:	Dec/18/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[180]
	Diastolic:	[66]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[35]

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

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**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

1.	Date:	Dec/19/2020
----	-------	-------------

**Vital Signs Details**

2.a	Record Identifier:	1
	Systolic:	[168]
	Diastolic:	[71]
	Respiratory Rate in respirations/minute:	[18]
	Heart Rate in beats/minute:	[71]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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### Vital Signs

1.	Date:	Dec/17/2020
----	-------	-------------

### Vital Signs Details

2-a	Record Identifier:	4
	Systolic:	[186]
	Diastolic:	[53]
	Respiratory Rate in respirations/minute:	[47]
	Heart Rate in beats/minute:	[40]

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**Header Text:** c4591001

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details		Form Instance
1.	Dec/17/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		Not Applicable	99.0	

**Header Text:** c4591001

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

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

**Form Version:** 14-Jan-2021 02:17

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details		Form Instance
2.	Dec/28/2020	<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

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

**Form Version:** 20-Feb-2021 02:11

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details		Form Instance
3.	Dec/19/2020	<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1	93.0	
4. DELETED		<b>Record Identifier:</b>	<b>Oxygen Saturation</b>	<a href="#">Repeating Pages</a>
		1		

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

1.	Date:	Dec/17/2020	<a href="#">Comments</a>
----	-------	-------------	--------------------------

**Vital Signs Details**

2.a	Record Identifier:	1	
	SPO2 Pulse Oximetry %	[99.0]	<a href="#">Comments</a>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 14-Jan-2021 02:17

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

1.	Date:	Dec/28/2020
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**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

1.	Date:	Dec/19/2020
----	-------	-------------

**Vital Signs Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Form Version:** 20-Feb-2021 02:11

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

1.	Date:	//
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**Vital Signs Details**

2-a	Record Identifier:	4
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

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

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	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>

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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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>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	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>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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[Form Comments](#)

[eCRF Audit Trail History](#)

### Concomitant Medications

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** IMAGING

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Dec/17/2020	CHEST	X-RAY	ABNORMAL <i>If abnormal, specify findings:</i>  Mild cardiomegaly. Mild vascular congestion and interstitial edema is questioned. No focal lung consolidation, pleural fluid or pneumothorax.	<a href="#">Repeating Pages</a>
2.	Dec/17/2020	HEAD	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i>  No acute intracranial process. Mild atrophy and chronic small vessel ischemic changes.	<a href="#">Repeating Pages</a>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** IMAGING

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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[Form Audit Trail](#)

### Imaging

1.	Date of Assessment:	Dec/17/2020	<a href="#">Comments</a>
2.	Location of Assessment:	CHEST	<a href="#">Comments</a>
3.	Type of Imaging Exam:	X-RAY	<a href="#">Comments</a>
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Mild cardiomegaly. Mild vascular congestion and interstitial edema is questioned. No focal lung consolidation, pleural fluid or pneumothorax.]	<a href="#">Comments</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** IMAGING

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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[Form Audit Trail](#)

### Imaging

1.	Date of Assessment:	Dec/17/2020
2.	Location of Assessment:	HEAD
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	ABNORMAL If abnormal, specify findings: [No acute intracranial process. Mild atrophy and chronic small vessel ischemic changes.]

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Dec/18/2020
2.	Erroneous Visit	ERRONEOUS VISIT

**COVID-19 Illness Visit**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** MICROBIOLOGY SPECIMEN

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date of Collection	Specimen Type	Specimen Collection Location	Assay Code and Description	Device Type	Form Instance
1.						<a href="#">Repeating Pages</a>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** MICROBIOLOGY SPECIMEN

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Microbiology Specimen**

1.	Actual Date of Collection:	//
2.	Specimen Type:	
3.	Specimen Collection Location:	
4.	Assay Code and Description:	
5.	Device Type:	
6.	Trade Name:	
7.	Test Result:	
8.	Comments/Findings /Details:	[ ]
9.	Trade Name Other, Specify:	[ ]

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** RESPIRATORY TREATMENT

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** RESPIRATORY TREATMENT

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Respiratory Treatment**

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** ILLNESS DETAILS - SEVERE

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category of Clinical Event:	Subcategory of Clinical Event	Diagnosis Obtained	Toxicity Grade	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** ILLNESS DETAILS - SEVERE

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Illness Details**

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	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>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

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

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category f or Lab Tes t	Vendor Nam e (DERIVED )	Collecti on Date :	Specim en Type	Lab Result			Form Instan ce
1.					Sponsor-Defi ned Identifie r	Te st:	Res ult:	<a href="#">Repeating Pages</a>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

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

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** VITAL SIGNS - COVID

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date:	Vital Signs Details			Form Instance
1.		<b>Record Identifier:</b>	<b>Systolic:</b>	<b>Diastolic:</b>	<a href="#">Repeating Pages</a>

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** VITAL SIGNS - COVID

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	Systolic:	[ ]
	Diastolic:	[ ]
	Respiratory Rate in respirations/minute:	[ ]
	Heart Rate in beats/minute:	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

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

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Vital Signs**

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

**Vital Signs Details**

2.	Record Identifier:	
	SPO2 Pulse Oximetry %	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** OXYGENATION PARAMETERS

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				<a href="#">Repeating Pages</a>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** OXYGENATION PARAMETERS

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Oxygenation Parameters**

1.	Date Time of Assessment:	//
2.	Arterial Blood Gases PaO2 (mmHg):	[ ]
3.	FiO2 (Fraction of Inhaled Oxygen):	[ ]

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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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.	Start Date:	//
6.	Ongoing?	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2

**Form:** IMAGING

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.					<a href="#">Repeating Pages</a>

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** IMAGING

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**Imaging**

1.	Date of Assessment:	//
2.	Location of Assessment:	
3.	Type of Imaging Exam:	
4.	Assessment:	

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/26/2021

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Date of Visit**

1.	Date of Visit	Jan/26/2021
2.	Erroneous Visit	

**COVID-19 Illness Visit**

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/26/2021**Form Version:** 22-Apr-2020 21:03**Site No:** 1131**Subject No:** 11311151**Generated By:** (b) (4)**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34[eCRF Audit Trail History](#)**Electronic Sample Tracking**

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Jan/26/2021
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	[BR0F9F]
5.b	Sample ID	[BS7XW8]
5.c	Sample ID	[BS7XW9]

**Header Text:** c4591001

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

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131    **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151    **Subject Initials:** ---

**Generated By:** (b) (4)    **Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Disposition - Treatment**

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Follow-Up - Unscheduled

**Form:** DISPOSITION - FOLLOW-UP

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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 **Form:** DATE OF VISIT - REPEAT SWAB  
- New Unscheduled Visit

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
1.	ADVERSE EVENT	1	complete heart block	Dec/8/2020 UNK:UNK	NO End Date Time:  Dec/19/2020 U NK:UNK	<a href="#">Repeating Pages</a>
2.	ADVERSE EVENT	2	hypokalemia	Dec/17/2020 UNK:UNK	NO End Date Time:  Dec/18/2020 U NK:UNK	<a href="#">Repeating Pages</a>
3.	ADVERSE EVENT	3	symptomatic bradycardia	Dec/8/2020 UNK:UNK	NO End Date Time:  Dec/19/2020 U NK:UNK	<a href="#">Repeating Pages</a>
4. DELETED			Not Applicable	Dec/17/2020 18:43	NO End Date Time:  Dec/19/2020 U NK:UNK	<a href="#">Repeating Pages</a>
5.	ADVERSE EVENT	5	hypertensive urgency	Dec/17/2020 UNK:UNK	NO End Date Time:  Dec/19/2020 U	<a href="#">Repeating Pages</a>

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**Visit:** Logs

**Form:** ADVERSE EVENT REPORT

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

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#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still Ongoing	Form Instance
					NK:UNK	
6.	ADVERSE EVENT	6	mild cardiomegaly	Dec/17/2020 UNK:UNK	YES	<a href="#">Repeating Pages</a>

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**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

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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)	[complete heart block]
4.	Start Date Time:	Dec/8/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/19/2020 UNK:UNK
6.	Toxicity Grade:	4

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7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect? NO</p> <p>Did this serious event result in death? NO</p> <p>Did this serious event require or prolong hospitalization? YES</p> <p>Did this serious event result in persistent or significant disability/incapacity? NO</p> <p>Is this serious event life threatening? YES</p> <p>Other medically important serious event NO</p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	NO
9.	<p>Is this event related to study treatment:</p>	<p>NOT RELATED</p> <p>If Not Related to study treatment(s), this event is due to: OTHER</p> <p>If Other, specify: [A-V conduction block]</p>
10.	<p>Latest Action Taken with Study Treatment:</p>	NOT APPLICABLE

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11.	Was a Concomitant Medication given?	YES
12.	Was a Non-Drug Treatment given?	YES
13.	What was the outcome of this adverse event?:	RECOVERED/RESOLVED WITH SEQUELAE
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020511089]

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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)	[hypokalemia]
4.	Start Date Time:	Dec/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/18/2020 UNK:UNK
6.	Toxicity Grade:	1

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

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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: CONCOMITANT DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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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	[ ]

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**Form Status:** Data Complete, Frozen

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[3]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[symptomatic bradycardia]
4.	Start Date Time:	Dec/8/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/19/2020 UNK:UNK
6.	Toxicity Grade:	2

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**Subject No:** 11311151

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**Form:** ADVERSE EVENT REPORT

**Form Status:** Data Complete, Frozen

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**Subject Initials:** ---

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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: [complete heart block]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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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	[ ]

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### Adverse Event Report

1.	Category:		
2.	AE ID:	[ ]	
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	Not Applicable _____ [ ]	<a href="#">Comments</a>
4.	Start Date Time:	<del>Dec/17/2020 18:43</del>	
5.	Is the adverse event still ongoing?	<del>NO</del> <del>End Date Time:</del> <del>Dec/19/2020 UNK:UNK</del>	
6.	Toxicity Grade:	4	

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

7.	<p>Is the adverse event serious?</p> <p>If Yes, NOTIFY PFIZER IMMEDIATELY.</p> <p>Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).</p>	<p><del>YES</del></p> <p><del>Is this serious event associated with congenital anomaly or birth defect?</del></p> <p><del>NO</del></p> <p><del>Did this serious event result in death?</del></p> <p><del>NO</del></p> <p><del>Did this serious event require or prolong hospitalization?</del></p> <p><del>YES</del></p> <p><del>Did this serious event result in persistent or significant disability/incapacity?</del></p> <p><del>NO</del></p> <p><del>Is this serious event life threatening?</del></p> <p><del>YES</del></p> <p><del>Other medically important serious event</del></p> <p><del>YES</del></p>
8.	<p>Is this adverse event the result of a study Medication Error?</p> <p>If Yes, record the type of medication error on the Medication Error Log.</p>	<p><del>NO</del></p>

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

9.	Is this event related to study treatment:	<del>NOT RELATED</del> <del>If Not Related to study treatment(s), this event is due to:</del> <del>OTHER</del> <del>If Other, specify:</del> <del>[av conduction block]</del>
10.	Latest Action Taken with Study Treatment:	<del>NOT APPLICABLE</del>
11.	Was a Concomitant Medication given?	<del>YES</del>
12.	Was a Non-Drug Treatment given?	<del>YES</del>
13.	What was the outcome of this adverse event?:	<del>RECOVERED/RESOLVED</del>
14.	Did the adverse event cause the subject to be discontinued from the study?	<del>NO</del>
15.	Serious Adverse Event Number: For Pfizer Use Only	[ ]

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[5]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[hypertensive urgency]
4.	Start Date Time:	Dec/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	NO End Date Time: Dec/19/2020 UNK:UNK
6.	Toxicity Grade:	2

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**Form Status:** Data Complete, Frozen

**Site No:** 1131

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**Subject Initials:** ---

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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: [Heart Block]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE

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**Subject Initials:** ---

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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	[ ]

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### Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[6]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[mild cardiomegaly]
4.	Start Date Time:	Dec/17/2020 UNK:UNK
5.	Is the adverse event still ongoing?	YES
6.	Toxicity Grade:	1

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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: CONCOMITANT NON-DRUG TREATMENT
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	NO

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12.	Was a Non-Drug Treatment given?	NO
13.	What was the outcome of this adverse event?:	NOT RECOVERED/NOT 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	[ ]

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**Visit:** Logs

**Form:** MEDICATION ERROR

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** MEDICATION ERROR

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

**Form Status:** Not Started

**Site No:** 1131

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**Subject No:** 11311151

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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	[ ]

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**Visit:** Logs

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

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

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**Subject No:** 11311151

**Subject Initials:** ---

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

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

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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

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

**Form Status:** Not Started

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**Subject Initials:** ---

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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:	//

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**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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**Subject No:** 11311151

**Subject Initials:** ---

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

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** CONCOMITANT MEDICATIONS - PROHIBITED

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**Form Status:** Not Started

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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?	

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

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**Form:** RADIATION TREATMENT

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**Form Status:** Not Started

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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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?	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs

**Form:** TRANSFUSIONS

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** TRANSFUSIONS

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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?	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Unplanned Vaccination -  
Unscheduled

**Form:** CONTACT OUTCOME - MONTH 1

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**Contact Outcome**

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

**Header Text:** c4591001

**Visit:** V201\_SURVEIL\_CONSENT - **Form:** DATE OF VISIT  
Unscheduled

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**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:** V201\_SURVEIL\_CONSENT -  
Unscheduled

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

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

**Form Status:** Not Started

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131      **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

Date of Visit		
1.	Date of Visit	Jan/18/2021
2.	Erroneous Visit	

**Header Text:** c4591001

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

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

**Site No:** 1131      **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:34

[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:** TREATMENT UNBLINDED

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Treatment Unblinded**

1.	Date Treatment Unblinded :	Jan/18/2021
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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Subject Status**

1.	Subject Status	FOLLOW-UP
2.	Subject Status Date	Nov/3/2020

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[eCRF Audit Trail History](#)

**Casebook Signature Form**

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

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

[Audit Trail](#)

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

- CRF\_Sign
- CRF\_Sign\_1

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

**Header Text:** c4591001

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

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Sep-08-2020 20:51:20 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	no inclusion or exclusion criteria met <hr/> Not Applicable

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
1.h	Sep-09-2020 10:35:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	rarely needs albuterol inhaler and no daily medication

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
1.h	Sep-09-2020 10:35:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	rarely needs albuterol inhaler and no daily medication

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
1.h	Sep-09-2020 10:35:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	rarely needs albuterol inhaler and no daily medication

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** GENERAL MEDICAL HISTORY - Comments

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

Item	Date	User	Comment
1.h	Sep-09-2020 10:35:47 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	rarely needs albuterol inhaler and no daily medication

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
2	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
3	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
4	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
5	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
6	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
7	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
8	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
9	Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
1	Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
2	Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
3	Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
4	Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
5	Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - Comments

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
6	Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
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**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete, Frozen

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**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

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Item	Date	User	Comment
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**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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

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

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

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

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**Header Text:** c4591001

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

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

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Item	Date	User	Comment
Form	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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

**Form Status:** Data Complete, Frozen

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Item	Date	User	Comment
5.b	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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CHEMISTRY - Comments

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**Subject No:** 11311151

**Subject Initials:** ---

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Item	Date	User	Comment
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**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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CHEMISTRY - Comments

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Item	Date	User	Comment
5.c	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5.c	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5.c	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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CHEMISTRY - Comments

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Item	Date	User	Comment
5.d	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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CHEMISTRY - Comments

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Item	Date	User	Comment
5.d	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Item	Date	User	Comment
5.d	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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CHEMISTRY - Comments

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Item	Date	User	Comment
5.d	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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CHEMISTRY - Comments

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Item	Date	User	Comment
5.e	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

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Unscheduled Visit on Dec/16/2020

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

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Item	Date	User	Comment
5.e	Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

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Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

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**Header Text:** c4591001

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

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

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

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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

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5.h	Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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Form	Dec-23-2020 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

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**Form:** VITAL SIGNS - COVID - Comments

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**Form:** VITAL SIGNS - PULSE OX ROOM AIR -  
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**Form Version:** 21-Aug-2020 02:51

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**Form:** OXYGENATION PARAMETERS - Comments

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Form	Dec-23-2020 12:05:42 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6) [Redacted]	Not Applicable

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

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Item	Date	User	Comment
3	Feb-05-2021 14:13:10 (UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Not Applicable

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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

- CRF\_Sign
- CRF\_Sign\_1

Name	Signature Meaning	Date	Type	Action
(b) (6)	N/A	Jan-22-2021 13:06:22 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated

**Affidavit:**

N/A

William Randall	Approved	Jan-22-2021 12:43:43 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
-----------------	----------	--	------	--------

**Affidavit:**

By my dated signature below, I, WilliamRandall, 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	Dec-17-2020 09:42:34 (UTC-05:00) Eastern Time (US & Canada)		Edit - All signatures invalidated
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form:** CASEBOOK SIGNATURE FORM - Signature  
History

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

**Form Status:** Data Complete, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**Affidavit:**

N/A

William Randall	Approved	Nov-06-2020 19:46:15 (UTC-05:00) Eastern Time (US & Canada)	BOOK	Signed
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**Affidavit:**

By my dated signature below, I, WilliamRandall, 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.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Select appropriate response - Protocol version*

Date	Location	User	Value	Reason
Sep-08-2020 20:50:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 24 JUL 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-08-2020 20:50:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> STAGE 3 COHORTS	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

**Form:** MAIN INFORMED CONSENT - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Consent Was:**

Date	Location	User	Value	Reason
Sep-08-2020 20:50:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OBTAINED Date Written Consent Obtained  Sep/8/2020	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** COHORT\_SELECTION

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** DEMOGRAPHY - eCRF Audit Trail History

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Subject ID**

Date	Location	User	Value	Reason
Sep-08-2020 20:50:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11311151	Item copied from previous form

**2. Birth Date:**

Date	Location	User	Value	Reason
Sep-08-2020 20:50:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> (b) (6) 1937	Enrollment Entry

**3. Sex:**

Date	Location	User	Value	Reason
Sep-08-2020 20:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> MALE	Initial Entry

**4. Ethnicity:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Sep-08-2020 20:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT HISPANIC OR LATINO(A) OR OF S PANISH ORIGIN	Initial Entry
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**5. Race: (Check X all that apply):**

Date	Location	User	Value	Reason
Sep-08-2020 20:51:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> WHITE	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-08-2020 20:51:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	<b>Data Entry:</b> Sep/8/2020	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** DISPOSITION - SCREENING - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Completion/Discontinuation/Death**

Date	Location	User	Value	Reason
Sep-08-2020 20:51:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Sep-08-2020 20:51:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SCREENING	Initial Entry

**3. Status:**

Date	Location	User	Value	Reason
Sep-08-2020 20:51:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)*1.a*

Date	Location	User	Value	Reason
Sep-09-2020 10:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 1 <b>Number:</b> <b>Medical History Term:</b> hearing loss in both ears <b>Start Date:</b> UNK/UNK/1970 <b>Ongoing:</b> YES	Initial Entry

*1.a Line/MH Number:*

Date	Location	User	Value	Reason
Sep-09-2020 10:32:00 (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
Sep-09-2020 10:32:00 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hearing loss in both ears	Initial Entry

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: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

& Canada)

**1.a Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1970	Initial Entry

**1.a Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**1.b**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 2 <b>H Number:</b> <b>Medical History</b> hearing devi ce wearer in <b>Term:</b> both ears <b>Start Date:</b> UNK/UNK/ 2014	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Ongoing YES</b>	
			:	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**1.b Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:20 (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
Sep-09-2020 10:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hearing device wear r in both ears	Initial Entry

**1.b Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2014	Initial Entry

**1.b Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:20	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*I.c*

Date	Location	User	Value	Reason
Sep-09-2020 10:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N umber:</b> 3 <b>Medical History Term:</b> myopia <b>Start Date:</b> UNK/UNK/1953 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

***1.c Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:32:31 (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-09-2020 10:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> myopia	Initial Entry

***1.c Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:32:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1953	Initial Entry

***1.c Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:32:31	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*1.d*

Date	Location	User	Value	Reason
Sep-09-2020 10:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N umber:</b> 4 <b>Medical History Term:</b> glaucoma <b>Start Date:</b> UNK/UNK/2015 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** V1\_DAY1\_VAX1\_L**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Locked, Frozen, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**1.d Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

**1.d Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> glaucoma	Initial Entry

**1.d Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

**1.d Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:32:52	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*I.e*

Date	Location	User	Value	Reason
Sep-09-2020 10:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 5 <b>H Numb</b> <b>er:</b> <b>Medical</b> cataract surg <b>History</b> ery in both e <b>Term:</b> yes <b>Start Da</b> UNK/UNK/ <b>te:</b> 2016 <b>Ongoing</b> NO : End Date:  UNK/UN K/2016	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.e Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:14 (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
Sep-09-2020 10:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cataract surgery in b oth eyes	Initial Entry

***1.e Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

***1.e Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:14	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	End Date:  UNK/UNK/2016
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*If*

Date	Location	User	Value	Reason
Sep-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 6</b> <b>umber:</b> <b>Medical His</b> chronic <b>tory Term:</b> dry eye <b>Start Date:</b> UNK/U NK/201 5 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.f Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:30 (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
Sep-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> chronic dry eye	Initial Entry

***1.f Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2015	Initial Entry

***1.f Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:30	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*I.g*

Date	Location	User	Value	Reason
Sep-09-2020 10:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 7 <b>Number:</b> <b>Medical History Term:</b> allergic rhinitis, seasonal <b>Start Date:</b> UNK/UNK/1970 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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**Site No:** 1131

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.g Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

***1.g Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> allergic rhinitis, seas onal	Initial Entry

***1.g Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1970	Initial Entry

***1.g Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:33:56	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*1.h*

Date	Location	User	Value	Reason
Sep-09-2020 10:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 8 <b>Number:</b> <b>Medical History Term:</b> moderate in intermittent asthma <b>Start Date:</b> UNK/UNK /1985 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**1.h Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 10:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> moderate intermitten t asthma	Initial Entry

**1.h Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:34:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1985	Initial Entry

**1.h Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:34:58	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

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(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*Li*

Date	Location	User	Value	Reason
Sep-09-2020 10:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 9 <b>Number:</b> <b>Medical History Term:</b> heart attack <b>m:</b> <b>Start Date</b> UNK/UNK : K/1990 <b>Ongoing:</b> NO End Date : UNK/UNK NK/1990 0	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

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

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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.i Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:36:31 (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-09-2020 10:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> heart attack	Initial Entry

***1.i Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:36:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

***1.i Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:36:31	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	End Date:  UNK/UNK/1990
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*I.j*

Date	Location	User	Value	Reason
Sep-09-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 10</b> <b>umber:</b> <b>Medical Hi</b> high bloo <b>story Term</b> d pressur : e <b>Start Date:</b> UNK/UN K/1990 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.j Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 10	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> high blood pressure	Initial Entry

***1.j Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

***1.j Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:36:48	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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*I.k*

Date	Location	User	Value	Reason
Sep-09-2020 10:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 11</b> <b>umber:</b> <b>Medical Hi edema in</b> <b>story Term both feet</b> <b>:</b> <b>Start Date:</b> UNK/U NK/2016 <b>Ongoing:</b> YES	Initial Entry

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Header Text: c4591001

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Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

**1.k Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 11	Initial Entry

**1.k Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> edema in both feet	Initial Entry

**1.k Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2016	Initial Entry

**1.k Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:10	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**1.1**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 12 <b>Number:</b> <b>Medical History Term:</b> mixed by perlipdem ia <b>Start Date:</b> UNK/UNK/1990 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

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Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

**1.1 Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 12	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 10:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mixed hyperlipdemi a	Initial Entry

**1.1 Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1990	Initial Entry

**1.1 Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:25	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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***I.m***

Date	Location	User	Value	Reason
Sep-09-2020 10:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/M</b> 13 <b>H Num</b> <b>ber:</b> <b>Medical</b> atherosclero <b>History</b> sis in both c <b>Term:</b> arotid arteri es <b>Start D</b> UNK/UNK/ <b>ate:</b> 2018 <b>Ongoin</b> YES <b>g:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

**1.m Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 13	Initial Entry

**1.m Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> atherosclerosis in both carotid arteries	Initial Entry

**1.m Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.m Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:37:59	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

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**Subject Initials:** ---

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

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(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*I.n*

Date	Location	User	Value	Reason
Sep-09-2020 10:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 14 <b>Number:</b> <b>Medical Hi</b> recurrent <b>story Term</b> heartburn : <b>Start Date:</b> UNK/U NK/2018 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

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Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

**1.n Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 14	Initial Entry

**1.n Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-09-2020 10:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> recurrent heartburn	Initial Entry

**1.n Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:38:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

**1.n Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:38:18	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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***1.o***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-09-2020 10:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 15 <b>Number:</b> <b>Medical History</b> chronic kid ney disease <b>Term:</b> , stage 3 <b>Start Date:</b> UNK/UNK /2010 <b>Ongoing</b> YES :	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

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**1.o Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 15	Initial Entry

**1.o Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-09-2020 10:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> chronic kidney disea se, stage 3	Initial Entry

**1.o Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:38:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.o Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:38:35	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*I.p*

Date	Location	User	Value	Reason
Sep-09-2020 10:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 16 <b>Number:</b> <b>Medical Hi</b> urinary in <b>story Term</b> continenc : e <b>Start Date:</b> UNK/UN K/2011 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

***1.p Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 16	Initial Entry

***1.p Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> urinary incontinence	Initial Entry

***1.p Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:38:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

***1.p Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:38:52	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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***I.q***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-09-2020 10:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 17 <b>Number:</b> <b>Medical History Term</b> erectile dysfunction <b>Start Date:</b> UNK/UNK/2010 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

**1.q Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 17	Initial Entry

**1.q Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-09-2020 10:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> erectile dysfunction	Initial Entry

**1.q Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:39:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

**1.q Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:39:12	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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***I.r***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Sep-09-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/</b> 18 <b>MH N</b> <b>umber</b> : <b>Medic</b> benign prosta <b>al Hist</b> tic hypertroph <b>ory Te</b> y with urinary <b>rm:</b> obstruction <b>Start</b> UNK/UNK/2 <b>Date:</b> 010 <b>Ongoi</b> YES <b>ng:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

***1.r Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 18	Initial Entry

***1.r Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> benign prostatic hypertrophy with urinary obstruction	Initial Entry

***1.r Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:39:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2010	Initial Entry

***1.r Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:39:40	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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*I.s*

Date	Location	User	Value	Reason
Sep-09-2020 10:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/</b> 19 <b>MH</b> <b>Num</b> <b>ber:</b> <b>Medi</b> transient ischem <b>cal</b> ic attacks, more <b>Hist</b> than one per sub <b>ory</b> ject, but not clea <b>Ter</b> r on specific nu <b>m:</b> mber <b>Start</b> UNK/UNK/201 <b>Date</b> 8 : <b>Ong</b> NO <b>oing:</b> End Date:  UNK/UNK/2 018	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

***1.s Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 19	Initial Entry

***1.s Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> transient ischemic at tacks, more than one per subject, but not c lear on specific num ber	Initial Entry

***1.s Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2018	Initial Entry

***1.s Ongoing:***

Date	Location	User	Value	Reason
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**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Sep-09-2020 10:41:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date:  UNK/UNK/2018	Initial Entry
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*I.t*

Date	Location	User	Value	Reason
Sep-09-2020 10:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH N 20</b> <b>umber:</b> <b>Medical Hi</b> chronic <b>story Term:</b> anemia <b>Start Date:</b> UNK/U NK/201 1 <b>Ongoing:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

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Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

*1.t Line/MH Number:*

Date	Location	User	Value	Reason
Sep-09-2020 10:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 20	Initial Entry

*1.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:*

Date	Location	User	Value	Reason
Sep-10-2020 17:37:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Sep-10-2020 15:52:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Per coordinator, subject did not receive blood products from 60 days prior to study visit and receipt of drug.
Sep-10-2020 15:29:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - CHRONIC ANEMIA is reported as Ongoing. Please confirm the subject did not receive

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

				blood products from 60 days prior to study drug and throughout the study, as this is prohibited per protocol.
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Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

***1.t Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> chronic anemia	Initial Entry

***1.t Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

***1.t Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

***1.u***

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

<p>Sep-09-2020 10:41:44 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>auto calc (autocalc)</p>	<p><b>Data Entry:</b> <b>Line/MH</b> 21 <b>Number:</b> <b>Medical History Term:</b> osteoarthritis in both hands <b>Start Date:</b> Mar/UNK/2020 <b>Ongoing:</b> YES</p>	<p>Initial Entry</p>
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.u Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 21	Initial Entry

***1.u Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> osteoarthritis in both hands	Initial Entry

***1.u Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Mar/UNK/2020	Initial Entry

***1.u Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:41:44	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

*I.v*

Date	Location	User	Value	Reason
Sep-09-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 22 <b>Number:</b> <b>Medical History Term:</b> prostate cancer <b>m:</b> <b>Start Date</b> UNK/UNK/2011 <b>Ongoing:</b> NO End Date : UNK/UNK/2011	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.v Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 22	Initial Entry

***1.v Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> prostate cancer	Initial Entry

***1.v Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

***1.v Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:42:03	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	End Date:  UNK/UNK/2011
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*I.w*

Date	Location	User	Value	Reason
Sep-09-2020 10:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/</b> 23 <b>MH N</b> <b>umber</b> <b>:</b> <b>Medic</b> tobacco use, p <b>al Hist</b> ast, cigarettes, <b>ory Te</b> 0.5 pack per d <b>rm:</b> ay <b>Start</b> UNK/UNK/19 <b>Date:</b> 58 <b>Ongoi</b> NO <b>ng:</b> End Date:  UNK/UNK /1964	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.w Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 23	Initial Entry

***1.w Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> tobacco use, past, cig arettes, 0.5 pack per day	Initial Entry

***1.w Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:42:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1958	Initial Entry

***1.w Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:42:44	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	End Date:  UNK/UNK/1964
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*I.x*

Date	Location	User	Value	Reason
Sep-09-2020 10:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 24 <b>Number:</b> <b>Medical</b> deviated se <b>History T</b> ptum repair <b>erm:</b> <b>Start Dat</b> UNK/UNK <b>e:</b> /1970 <b>Ongoing:</b> NO End Date:  UNK/U NK/197 0	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.x Line/MH Number:***

Date	Location	User	Value	Reason
Sep-09-2020 10:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 24	Initial Entry

***1.x Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:***

Date	Location	User	Value	Reason
Sep-09-2020 10:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> deviated septum repair	Initial Entry

***1.x Start Date:***

Date	Location	User	Value	Reason
Sep-09-2020 10:43:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/1970	Initial Entry

***1.x Ongoing:***

Date	Location	User	Value	Reason
Sep-09-2020 10:43:05	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	End Date:  UNK/UNK/1970
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*I.y*

Date	Location	User	Value	Reason
Sep-09-2020 10:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Line/MH</b> 25 <b>Number:</b> <b>Medical H</b> prostatecto <b>istory Ter</b> my <b>m:</b> <b>Start Date</b> UNK/UN : K/2011 <b>Ongoing:</b> NO End Date :  UNK/U NK/201 1	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**1.y Line/MH Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 25	Initial Entry

**1.y Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:**

Date	Location	User	Value	Reason
Sep-09-2020 10:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> prostatectomy	Initial Entry

**1.y Start Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:43:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> UNK/UNK/2011	Initial Entry

**1.y Ongoing:**

Date	Location	User	Value	Reason
Sep-09-2020 10:43:31	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** GENERAL MEDICAL HISTORY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	End Date:  UNK/UNK/2011	
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**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2. Weight:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 78.0	Initial Entry

**3. Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> kg	Initial Entry

**4. Height:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 161.4	Initial Entry
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**5. Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> cm	Initial Entry

**6. Body Mass Index:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 29.9	Initial Entry

**7.a**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Temperature:</b> 36.8	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Temperatu C re Unit:</b> <b>Temperatu ORAL re Locatio CAVIT n:: Y</b>
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**7.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7.a Temperature:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.8	Initial Entry

**7.a Unit:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** VITAL SIGNS - BASELINE - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**7.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** RANDOMIZATION - eCRF Audit Trail History

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Randomization Date :**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020	Initial Entry

**2. Randomization Number:**

Date	Location	User	Value	Reason
Sep-09-2020 10:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 255113	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

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

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-08-2020 21:07:41 (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-08-2020 21:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Sep-08-2020 21:07:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 21:07:41 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-08-2020 21:07:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/8/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-08-2020 21:07:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BN6DS : B	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Sep-08-2020 21:07:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6DSB	Initial Entry

5.b

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Sep-08-2020 21:07:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BL9W0 : M	Initial Entry
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**5.b Sample ID**

Date	Location	User	Value	Reason
Sep-08-2020 21:07:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9W0M	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Sep-08-2020 21:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BL9W0 : N	Initial Entry

**5.c Sample ID**

Date	Location	User	Value	Reason
Sep-08-2020 21:08:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BL9W0N	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-08-2020 21:08:20 (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-08-2020 21:08:20 (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-08-2020 21:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-08-2020 21:08:20 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-08-2020 21:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection: Sep/8/2020	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Sep-08-2020 21:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BN6DZ : J	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-08-2020 21:08:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BN6DZJ	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-09-2020 10:45:02 (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-09-2020 10:45:02 (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-09-2020 10:45:02 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V1\_DAY1\_VAX1\_L

Form: VACCINATION - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

Sep-09-2020 10:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/8/2020 21:17	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-09-2020 10:45:02 (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-09-2020 10:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-09-2020 10:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-09-2020 10:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-09-2020 10:45:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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

**Form:** REACTOGENICITY DIARY - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Select appropriate response - Reactogenicity diary collection*

Date	Location	User	Value	Reason
Sep-09-2020 10:45:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO - REACTOGEN ICITY E-DIARY N OT COLLECTED F OR THIS SUBJECT	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Sep-29-2020 14:23:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date:**

Date	Location	User	Value	Reason
Sep-29-2020 14:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Sep-29-2020 14:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> <b>Temperature:</b> <b>Temperature Unit:</b> <b>Temperature Location:</b> <b>Y</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Sep-29-2020 14:24:17 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VITAL SIGNS - TEMP - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

**2.a Temperature:**

Date	Location	User	Value	Reason
Sep-29-2020 14:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.7	Initial Entry

**2.a Unit:**

Date	Location	User	Value	Reason
Sep-29-2020 14:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C	Initial Entry

**2.a Temperature Location:**

Date	Location	User	Value	Reason
Sep-29-2020 14:24:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ORAL CAVITY	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Sep-29-2020 14:24:26 (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 14:24:26 (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-29-2020 15:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-29-2020 14:24:26 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Sep-29-2020 14:24:26 (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 15:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BP9B2 : P	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Sep-29-2020 15:10:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP9B2P	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** VACCINATION - eCRF Audit Trail History

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Was there a temporary delay of vaccination?**

Date	Location	User	Value	Reason
Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**2. Treatment Name**

Date	Location	User	Value	Reason
Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLINDED THERAPY	Initial Entry

**3. Formulation:**

Date	Location	User	Value	Reason
Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INJECTION	Initial Entry

**4. Dose Date Time:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sep/29/2020 13:38	Initial Entry
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**5. Anatomical Location:**

Date	Location	User	Value	Reason
Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> DELTOID MUSCLE	Initial Entry

**6. Body Side:**

Date	Location	User	Value	Reason
Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> LEFT	Initial Entry

**7. Route:**

Date	Location	User	Value	Reason
Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> INTRAMUSCULAR	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V2\_VAX2\_L

**Form:** VACCINATION - eCRF Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**10. Timeframe Subject Was Observed**

Date	Location	User	Value	Reason
Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> THE PROTOCOL SPE CIFIED OBSERVATIO N PERIOD	Initial Entry

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

Date	Location	User	Value	Reason
Sep-29-2020 14:25:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** DATE OF VISIT - eCRF Audit Trail History

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Nov-03-2020 15:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Nov-03-2020 15:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Nov-03-2020 15:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SERUM	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Nov-03-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-03-2020 15:17:58 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: V3\_MONTH1\_POSTVAX2\_L Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

Site No: 1131 Site Name: (1131) PriMED Clinical Research

Subject No: 11311151 Subject Initials: ---

Generated By: (b) (4) Generated Time (GMT): 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Nov-03-2020 15:17:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Nov/3/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-03-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BS7XB : Y	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Nov-03-2020 18:13:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS7XBY	Initial Entry

5.b

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Nov-03-2020 18:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID</b> BS7XB : X	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Nov-03-2020 18:13:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS7XBX	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Nov-03-2020 18:13:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sample ID:</b> BP99ZF	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** V3\_MONTH1\_POSTVAX2\_L **Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History

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

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

*5.c Sample ID*

Date	Location	User	Value	Reason
Nov-03-2020 18:13:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BP99ZF	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Feb-01-2021 07:17:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Closed	Clinical query present on HEALTH CARE UTILIZATION form for same issue
Jan-28-2021 02:59:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Reissued:Candidate	Please review this query once data is entered on 'HOSPITALIZATION DETAILS' form.
Jan-27-2021 16:59:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Answered	This will be updated soon.
Jan-27-2021 08:53:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 4: Opened	DM: Kindly review and complete 'HOSPITALIZATION DETAILS' at this visit. Thank you.
Dec-24-2020 01:09:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Deleted	Sample not collected Nasal Swab Self and Nasal Swab

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-23-2020 23:01:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Dec-23-2020 12:16:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	information updated
Dec-23-2020 02:43:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	DM1: Thank you for response. Kindly complete 'COVID TEST' and 'ILL POTEN' forms under this visit once data is available and respond to the query.
Dec-23-2020 02:13:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Date of Assessment in the Signs and Symptoms form is entered
Dec-22-2020 16:04:19 (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.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Ans wered	Answer Auto Query
Dec-22-2020 02:37:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Rei ssued:Opene d	DM1: Kindly update the data once available, change query status to answered when data updated.
Dec-22-2020 01:37:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Rei ssued:Candid ate	Please review this query once data is entered on COVIE TEST, HEALCARE and ILL POTEN CRFs.
Dec-22-2020 00:19:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Rei ssued:Candid ate	per response "waiting on clarification from sit Physician". Please take action once data available
Dec-21-2020 13:39:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Ans wered	waiting on clarification from sit Physician
Dec-21-2020 13:38:38 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	waiting on clarification from sit Physician

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(US & Canada)				
Dec-21-2020 13:38:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	waiting on clarification from sit Physician
Dec-18-2020 06:25:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM: Kindly consider to update missing COVID TEST, HEALTHCARE, ILL POTEN forms or else clarify. Thank you.
Dec-18-2020 06:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Dec-18-2020 06:06:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Dec-17-2020 09:42:32 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

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

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

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(US & Canada)				form is missing. Please review and update as appropriate.
Dec-17-2020 09:42:32 (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.
Dec-17-2020 09:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/16/2020	Initial Entry

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

Date	Location	User	Value	Reason
Dec-17-2020 09:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_A	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

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

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

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/16/2020	Initial Entry

**2. Date of First Symptom Started:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/16/2020	Initial Entry

**3. Symptoms Ongoing?**

Date	Location	User	Value	Reason
Jan-26-2021 16:53:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO Date of Last Symptom Resolved: Dec/19/2020	New Information
Dec-22-2020 15:59:44	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	Date of Last Symptom Resolved:  Dec/UNK/2020
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**4.a**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> FEV ER <b>Symptom Present:</b> NO	Initial Entry

**4.a Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (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
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

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

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

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**4.b**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sympt</b> NEW OR I <b>oms:</b> NCREASE D COUGH  <b>Sympt</b> NO <b>om Pre</b> <b>sent:</b>	Initial Entry

**4.b Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED COUGH	Initial Entry

**4.b Was symptom present?**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.c**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sym</b> NEW OR IN <b>ptom</b> CREASD S <b>s:</b> HORTNESS OF BREATH  <b>Sym</b> NO <b>ptom</b> <b>Prese</b> <b>nt:</b>	Initial Entry
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**4.c Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED SHORTNESS O F BREATH	Initial Entry

**4.c Was symptom present?**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms:</b> CHIL LS <b>Symptom Pr NO</b> <b>esent:</b>	Initial Entry
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**4.d Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (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
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.e**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symp</b> NEW OR IN <b>toms:</b> CREATED MUSCLE P AIN	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

			Symp tom P resent :	
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**4.e Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED MUSCLE PAIN	Initial Entry

**4.e Was symptom present?**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**4.f**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sympt NEW LOSS oms: OF TASTE OR SMELL	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

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

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

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Sympt NO om Pr esent:</b>	
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**4.f Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW LOSS OF TAS TE OR SMELL	Initial Entry

**4.f Was symptom present?**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.g**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symp</b> NEW OR IN <b>toms:</b> CREATED SORE THR OAT	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

			Symp tom P resent :	
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**4.g Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEW OR INCREAS ED SORE THROAT	Initial Entry

**4.g Was symptom present?**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (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
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptoms DIARR : HEA Symptom NO Present:	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**4.h Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (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
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**4.i**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> VOMI : TING <b>Symptom</b> NO <b>Present:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**4.i Symptoms:**

Date	Location	User	Value	Reason
Dec-22-2020 15:59:44 (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
Dec-22-2020 15:59:44 (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
Dec-22-2020 16:00:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Symptom nasal co s - Other: ngestion	Initial Entry

**5.a Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-22-2020 16:00:39	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nasal congestion	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.b**

Date	Location	User	Value	Reason
Dec-22-2020 16:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Symptoms</b> nasal dr <b>- Other:</b> ainage	Initial Entry

**5.b Symptoms - Other Text:**

Date	Location	User	Value	Reason
Dec-22-2020 16:01:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nasal drainage	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
			Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - Audit Trail

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

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Jan-26-2021 16:13:46 (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 Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assay Code and Description:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5. Device Type:**

Date	Location	User	Value	Reason
Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

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

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**8. Comments/Findings/Details:**

Date	Location	User	Value	Reason
Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Dec-23-2020 12:15:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Actual Date of Collection:**

Date	Location	User	Value	Reason
Jan-26-2021 16:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/17/2021	Initial Entry

**2. Specimen Type:**

Date	Location	User	Value	Reason
Jan-26-2021 16:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> SWABBED MATER IAL	Initial Entry

**3. Specimen Collection Location:**

Date	Location	User	Value	Reason
Jan-26-2021 16:13:46 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-26-2021 16:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SEVERE ACUTE RES P SYNDROME CORO NAVIRUS 2	Initial Entry
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**5. Device Type:**

Date	Location	User	Value	Reason
Jan-26-2021 16:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SARS-COV-2 DIAGN OSTIC TEST	Initial Entry

**6. Trade Name:**

Date	Location	User	Value	Reason
Jan-26-2021 16:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> OTHER	Initial Entry

**7. Test Result:**

Date	Location	User	Value	Reason
Jan-26-2021 16:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NEGATIVE	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** MICROBIOLOGY SPECIMEN - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

**9. Trade Name Other, Specify:**

Date	Location	User	Value	Reason
Jan-26-2021 16:13:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> nalt unknown	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

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

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

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 16:04:19 (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
Dec-22-2020 16:04:19 (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
Dec-22-2020 16:04:19 (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:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

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

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

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Dec-22-2020 16:04:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> waiting on swab fro m subject	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

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

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

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

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Dec-22-2020 16:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Dec-22-2020 16:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> NASAL_SWAB	Initial Entry

**3. Sample Collected?**

Date	Location	User	Value	Reason
Dec-22-2020 16:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

**4. If no sample was collected or sample was not collected according to protocol, please provide reason:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Dec-22-2020 16:04:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> self swab	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1.a*

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Prac</b> SPEC <b>titioner:</b> IALI ST <b>Occurrence</b> NO <b>of Visits or</b> <b>Contacts:</b>	Initial Entry

*1.a Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (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
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.b***

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pr</b> EMER <b>actioner:</b> GENC Y ROO M <b>Occurrence</b> NO <b>of Visits</b> <b>or Contact</b> <b>s:</b>	Initial Entry

***1.b Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> EMERGENCY ROO M	Initial Entry

***1.b Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.c***

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Jan-26-2021 16:16:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of</b> PRIMAR <b>Practiti</b> Y CARE <b>oner:</b> PHYSICI AN <b>Occurre</b> YES <b>nce of V</b> <i>Number</i> <b>isits or</b> <i>of Visits</i> <b>Contact</b> <i>or Cont</i> <b>s:</b> <i>acts:</i>  1	New Information
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of</b> PRIMA <b>Practitio</b> RY CAR <b>ner:</b> E PHYS ICIAN <b>Occurre</b> NO <b>nce of Vi</b> <b>sits or C</b> <b>ontacts:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

***1.c Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> PRIMARY CARE P HYSICIAN	Initial Entry

***1.c Occurrence of Visits or Contacts:***

Date	Location	User	Value	Reason
Jan-26-2021 16:16:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES <i>Number of Visits o r Contacts:</i>  1	New Information
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.d***

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Pra</b> URGE <b>itioner:</b> NT C ARE	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Occurrence NO of Visits or Contacts:</b>	
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***1.d Physician or Healthcare Professional:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-22-2020 16:05:38 (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:***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***1.e***

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of P TELEPH ractice ONE CO r: NSULTA TION</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Occurrence of Visits or Contacts:</b>	
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*1.e Physician or Healthcare Professional:*

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (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
Dec-22-2020 16:05:38 (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
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Type of Practitioner:</b> OT HE R	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Occurrence of NO Visits or Contacts:</b>	
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***1.f Physician or Healthcare Professional:***

Date	Location	User	Value	Reason
Dec-22-2020 16:05:38 (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
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

***3. Has the subject been hospitalized due to potential COVID-19 illness?***

Date	Location	User	Value	Reason
Feb-19-2021 08:00:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021	ACV0PFEINFP6000	(b) (6)	Query 1: Answered	HOSP CRF

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

16:44:53 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		updated
Feb-16-2021 07:48:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clin: HOSP CRF is still pending. Please enter start/stop dates.
Feb-11-2021 17:57:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated
Feb-11-2021 14:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clin: Please enter dates of hospitalization in HOSP CRF. Also, if subject was hospitalized, weren't labs performed? Please enter in LAB CHEM and LAB HEM CRFs.
Feb-09-2021 16:43:37 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)				
Feb-08-2021 08:43:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Clin: Pending update.
Feb-05-2021 17:23:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this will be updated soon
Jan-29-2021 17:05:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: As subject was hospitalized, please complete HOSP, RESP TX, ILL SEVERE, LAB CHEM, LAB HEM, VITALS COV, PULSE OX, OXYGEN, VASOPRESS, and IMAGING CRFs as applicable.
Jan-26-2021 16:15:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Has the subject b een in intensive c are due to potenti	New Information

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

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

**Form:** HEALTH CARE UTILIZATION - eCRF Audit  
Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

			al COVID-19 illness?  NO	
Dec-22-2020 16:05:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HOSPITALIZATION DETAILS - Audit Trail

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

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-18-2021 16:44:21 (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 Dec/16/2020

**Form:** HOSPITALIZATION DETAILS - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Hospitalization Category:**

Date	Location	User	Value	Reason
Feb-18-2021 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HOSPITALIZATION S TATUS	Initial Entry

**2. Hospitalization Term:**

Date	Location	User	Value	Reason
Feb-18-2021 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HOSPITAL	Initial Entry

**3. Admission Date:**

Date	Location	User	Value	Reason
Feb-25-2021 09:06:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 17:24:05 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	All available information has been added.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** HOSPITALIZATION DETAILS - eCRF Audit  
Trail History

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

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

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

**Generated Time (GMT):** 29-Mar-2021 11:34

(US & Canada)				
Feb-19-2021 11:07:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	CLIQUERY: Hospitalization: This subject had COVID-19 Illness and was hospitalized. Please enter any available information (vital signs, pulse oxymet, respiratory treatment, lab results, imaging...). Please make every effort to obtain these information.
Feb-18-2021 16:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Dec/17/2020	Initial Entry

**4. Ongoing?**

Date	Location	User	Value	Reason
Feb-18-2021 16:44:21 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NO Discharge Date:	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** HOSPITALIZATION DETAILS - eCRF Audit  
Trail History

**Form Status:** Data Complete

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US  
& Canada)

Dec/19/2020

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail  
History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. What is the treatment Identifier?**

Date	Location	User	Value	Reason
Dec-22-2020 16:06:18 (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
Dec-22-2020 16:06:18 (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
Dec-22-2020 16:06:18 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** RESPIRATORY TREATMENT - eCRF Audit Trail  
History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5. Start Date:**

Date	Location	User	Value	Reason
Dec-22-2020 16:06:18 (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
Dec-22-2020 16:06:18 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** ILLNESS DETAILS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:52

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-23-2020 12:03:10 (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
Dec-23-2020 12:03:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**3. Toxicity Grade:**

Date	Location	User	Value	Reason
Dec-23-2020 12:03:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit  
Trail History

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

**1. Category of Clinical Event:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:02 (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
Dec-23-2020 12:06:02 (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
Dec-23-2020 12:06:02 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** ILLNESS DETAILS - SEVERE - eCRF Audit  
Trail History

**Form Version:** 17-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-23-2020 12:06:02 (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 Dec/16/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US  
& Canada)

**5.a Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fin ed Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.b LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.c LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.d LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.e LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.f LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:49

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:49

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

**5.g LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - Audit Trail

**Form Version:** 14-Jan-2021 02:30

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (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 Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMIST RY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-D</b> 329 <b>efined Ide</b> <b>ntifier:</b> <b>Test::</b> C Reactiv e Protein_ PX329 <b>Result::</b> <b>Not Done:</b> NOT DO : NE <b>Lab Norm</b> <b>al Range:</b>	Initial Entry
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_P X329	Initial Entry

**5.a Not Done:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (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
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 30 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Alanine A minotransf erase_PX3 0 <b>Result::</b> <b>Not Done</b> NOT DON <b>::</b> E <b>Lab Nor</b> <b>mal Rang</b> <b>e:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransf erase_PX30	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor- 28	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:30

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Defined Identifier:**

**Test::** Aspartate  
Aminotransferase\_PX2  
8

**Result::**

**Not Done** NOT DON  
:: E

**Lab Normal Range:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:30

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotran sferase_PX28	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-D 35	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**efined Identifier:**

**Test::** Alkaline P  
hosphatas  
e\_PX35

**Result::**

**Not Done:** NOT DO  
: NE

**Lab Normal Range:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatas e_PX35	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defi 21	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:30

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**ned Identifie  
r:**

**Test::** Bilirubi  
n\_PX2  
1

**Result::**

**Not Done::** NOT D  
ONE

**Lab Normal  
Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (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
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 47	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:30

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Defined Identifier:**

**Test::** Blood Urea Nitrogen  
\_PX47

**Result::** 43

**Not Done:**

:

**Lab Normal Range:** *Low*

*7*

**High:**

*High*  
*25*

*Unit*  
*mg/L*

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen _PX47	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 43	Initial Entry

**5.f LNMT**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)	(b) (4), (b) (6)	7	
		<i>High</i> 25	
		<i>Unit</i> mg/L	

**5.g**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def 48</b> <b>ined Identifier:</b> <b>Test::</b> Creatinine_PX4 8 <b>Result::</b> 2.0 <b>Not Done::</b> <b>Lab Normal Low</b> <b>Range:</b> 0.7  <i>High</i> 1.3  <i>Unit</i> mg/dL	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:30

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17 (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
Feb-11-2021 17:39:17 (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
Feb-11-2021 17:39:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2.0	Initial Entry

**5.g LNMT**

Date	Location	User	Value	Reason
Feb-11-2021 17:39:17	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Low	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:30

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	0.7	
			<i>High</i> 1.3	
			<i>Unit</i> mg/dL	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - Audit Trail

**Form Version:** 20-Feb-2021 02:26

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (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 Dec/16/2020

Form: LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

Form Version: 20-Feb-2021 02:26

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> CLINICAL CHEMIST RY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:29 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-D</b> 329 <b>efined Ide</b> <b>ntifier:</b> <b>Test::</b> C Reactiv e Protein_ PX329 <b>Result::</b> <b>Not Done:</b> NOT DO : NE <b>Lab Norm</b> <b>al Range:</b>	Initial Entry
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 329	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> C Reactive Protein_P X329	Initial Entry

**5.a Not Done:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (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
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-</b> 30 <b>Defined I</b> <b>dentifier:</b> <b>Test::</b> Alanine A minotransf erase_PX3 0 <b>Result::</b> <b>Not Done</b> NOT DON <b>::</b> E <b>Lab Nor</b> <b>mal Rang</b> <b>e:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 30	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alanine Aminotransfe rase_PX30	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor- 28	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Defined Identifier:**

**Test::** Aspartate  
Aminotransferase\_PX2  
8

**Result::**

**Not Done** NOT DON  
**::** E

**Lab Normal Range:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 28	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Aspartate Aminotrans ferase_PX28	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-D 35	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**efined Identifier:**

**Test::** Alkaline P  
hosphatas  
e\_PX35

**Result::**

**Not Done:** NOT DO  
:  
NE

**Lab Normal Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 35	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Alkaline Phosphatase _PX35	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defi 21	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**ned Identifie  
r:**

**Test::** Bilirubi  
n\_PX2  
1

**Result::**

**Not Done::** NOT D  
ONE

**Lab Normal  
Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (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
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Bilirubin_PX21	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-D 47	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**efined Identifier:**

**Test::** Blood Urea  
Nitrogen  
\_PX47

**Result::** 40

**Not Done:**

:

**Lab Normal Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 47	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Blood Urea Nitrogen_ PX47	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Mar-05-2021 03:38:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:55:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form Version:** 20-Feb-2021 02:26**Site No:** 1131**Subject No:** 11311151**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

				abnormal. this has been stated throughout audit trail multiple times. please do not constantly re-query if same question has been addressed. CRA does not need to be contacted
Feb-25-2021 12:26:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thank you for your response. Kindly connect with your CRA for any further assistance if needed and update CRF as appropriate. Else clarify.
Feb-25-2021 08:41:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-25-2021 07:25:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM 1: Kindly verify data and consider updating missing ranges or else clarify. Thank you.
Feb-24-2021 17:10:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.
Feb-24-2021 17:10:08 (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.
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 40	Initial Entry

5.g

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 17:12:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-D</b> 48 <b>efined Iden</b> <b>tifier:</b> <b>Test::</b> Creatin ine_PX 48 <b>Result::</b> 1.7 <b>Not Done::</b> <b>Lab Norm</b> <b>al Range:</b>	New Information
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-D</b> 48 <b>efined Iden</b> <b>tifier:</b> <b>Test::</b> Creatin ine_PX 48 <b>Result::</b> <b>Not Done::</b> NOT D ONE <b>Lab Norm</b> <b>al Range:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:26

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:10:08 (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
Feb-24-2021 17:10:08 (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
Mar-05-2021 03:52:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:56:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form Version:** 20-Feb-2021 02:26**Site No:** 1131**Subject No:** 11311151**Generated By:** (b) (4)**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History**Form Status:** Data Complete, Frozen**Site Name:** (1131) PriMED Clinical Research**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 11:34

				abnormal. this has been stated throughout audit trail multiple times. please do not constantly re-query if same question has been addressed. CRA does not need to be contacted
Feb-25-2021 12:26:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thank you for your response. Kindly connect with your CRA for any further assistance if needed and update CRF as appropriate. Else clarify.
Feb-25-2021 08:41:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History**Form Version:** 20-Feb-2021 02:26**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-25-2021 07:26:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM 1: Kindly verify data and consider updating missing ranges or else clarify. Thank you.
Feb-24-2021 17:12:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.
Feb-24-2021 17:12:07 (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.
Feb-24-2021 17:12:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1.7	New Information

**5.g Not Done:**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
CHEMISTRY - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:26

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 17:12:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	New Information
Feb-24-2021 17:10:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> NOT DONE	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

**1. Lab Panel:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Laboratory Name and Address**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.a**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US  
& Canada)

**5.a Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.a LNMT**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fin ed Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.b Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.b LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.c LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.d Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.d LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.e LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.f LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.g LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.h LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble <b>Lab Norma</b> Not A <b>l Range:</b> pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**5.i LNMT**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De</b> Not A <b>fined Identi</b> pplica <b>fier:</b> ble <b>Test::</b> Not A pplica ble <b>Result::</b> Not A pplica ble <b>Not Done::</b> Not A pplica ble	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 21-Aug-2020 02:51

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Lab Normal Range:</b>	Not Applicable	
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Result:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Dec-23-2020 12:06:49	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**5.j LNMT**

<b>Date</b>	<b>Location</b>	<b>User</b>	<b>Value</b>	<b>Reason</b>
Dec-23-2020 12:06:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - Audit Trail

**Form Version:** 14-Jan-2021 02:24

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (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 Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 17:16:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-D 1</b> <b>efined Ide</b> <b>ntifier:</b> <b>Test::</b> Hemogl obin_P X1 <b>Result::</b> 12.5 <b>Not Done:</b> : <b>Lab Norm Low</b> <b>al Range:</b> 13.1  <i>High</i> 17.6  <i>Unit</i> /uL	Initial Entry
Feb-24-2021 17:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-D 1</b> <b>efined Iden</b> <b>tifier:</b> <b>Test::</b> Hemog lobin_P X1 <b>Result::</b> 12.5 <b>Not Done::</b> <b>Lab Norm</b> <b>al Range:</b>	New Information
Feb-11-2021 17:42:29	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)			<b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemoglobin_PX1 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>
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**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

**5.a Result:**

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-25-2021 02:57:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-24-2021 17:08:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.
Feb-24-2021 17:07:53 (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.
Feb-24-2021 17:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 12.5	New Information

**5.a Not Done:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 17:07:53 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.a LNMT**

Date	Location	User	Value	Reason
Feb-24-2021 17:16:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 13.1  <i>High</i> 17.6  <i>Unit</i> /uL	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-24-2021 17:16:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-De 2 fined Identi fier:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001  
**Visit:** POT\_COVID\_ILL 1 -  
 Unscheduled Visit on Dec/16/2020  
**Form Version:** 14-Jan-2021 02:24  
**Site No:** 1131  
**Subject No:** 11311151  
**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
 Hematology - eCRF Audit Trail History  
**Form Status:** Data Complete, Frozen  
**Site Name:** (1131) PriMED Clinical Research  
**Subject Initials:** ---  
**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Test::</b> Hemato crit_PX 2 <b>Result::</b> 36.9 <b>Not Done::</b> <b>Lab Norma</b> <i>Low</i> <b>l Range:</b> 39  <i>High</i> 51.5  <i>Unit</i> %	
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b><u>Data Entry:</u></b> <b>Sponsor-De</b> 2 <b>fined Identi</b> <b>fier:</b> <b>Test::</b> Hemato crit_PX 2 <b>Result::</b> 36.9 <b>Not Done::</b> <b>Lab Normal</b> <b>Range:</b>	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (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
Feb-11-2021 17:42:29 (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
Feb-12-2021 09:09:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-11-2021 17:53:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	lab ranges not given in the report

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-11-2021 17:42:29 (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.
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36.9	Initial Entry

**5.b LNMT**

Date	Location	User	Value	Reason
Feb-24-2021 17:16:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 39  <i>High</i> 51.5  <i>Unit</i> %	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def 3</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**ined Identifier:**

**Test::** Erythrocytes\_PX  
3

**Result::**

**Not Done::** NOT DONE

**Lab Normal Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Feb-24-2021 17:16:40	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sponsor-Def 5	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	<b>Identified Identifier:</b> <b>Test::</b> Platelets_PX5 <b>Result::</b> 129 <b>Not Done::</b> <b>Lab Normal Range:</b> <i>Low</i> 154 <i>High</i> 393 <i>Unit</i> /uL	
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Platelets_PX5 <b>Result::</b> 129 <b>Not Done::</b> <b>Lab Normal Range:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
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Feb-11-2021 17:53:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	lab ranges not given in the report

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-11-2021 17:42:29 (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.
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 129	Initial Entry

**5.d LNMT**

Date	Location	User	Value	Reason
Feb-24-2021 17:16:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <i>Low</i> 154  <i>High</i> 393  <i>Unit</i> /uL	Initial Entry

**5.e**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def 7</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**inded Identifier:**

**Test::** Leukocytes\_P  
X7

**Result::** 6.4

**Not Done::**

**Lab Normal Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Result:**

Date	Location	User	Value	Reason
Feb-19-2021 00:03:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 16:47:23 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Lab ranges and units not entered were not included in the hospital

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

				records. the CRF does not provide options for these labs.
Feb-15-2021 11:00:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Please consider to update the lab normal ranges with available unit from the CRF options. Kindly connect with CRA for any further assistance if needed.
Feb-12-2021 12:08:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	lab ranges not given in the report
Feb-12-2021 09:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Lab normal range (Low, high or Unit) is missing. Please complete data entry.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-11-2021 17:53:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	lab ranges not given in the report
Feb-11-2021 17:42:29 (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.
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 6.4	Initial Entry

5.f

Date	Location	User	Value	Reason
Feb-24-2021 17:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Sponsor-D</b> 608 <b>efined Ide</b> <b>ntifier:</b> <b>Test::</b> Neutrop hils_PX 608 <b>Result::</b> 68.2 <b>Not Done::</b>	New Information

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Lab Normal Range:</b>	
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> Test:: Neutrophils_PX 608 <b>Result:</b> <b>Not Done:</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

**5.f Result:**

Date	Location	User	Value	Reason
Feb-25-2021 02:58:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**5.f Result:**

Date	Location	User	Value	Reason
Feb-24-2021 17:14:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.
Feb-24-2021 17:13:49 (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.
Feb-24-2021 17:13:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 68.2	New Information

**5.f Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:13:49 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	New Information

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> 609 <b>Test::</b> Eosinophils_PX 609 <b>Result:</b> <b>Not Done:</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-De</b> 612	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Identified Identifier:**

**Test::** Monocytes\_PX61  
2

**Result::**

**Not Done::** NOT DONE

**Lab Normal Range:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 612	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.i**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def</b> 610	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**ined Identifier:**

**Test::** Basophi  
ls\_PX61  
0

**Result::**

**Not Done::** NOT D  
ONE

**Lab Normal  
Range:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-De 611	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 14-Jan-2021 02:24

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Identified Identifier:**

**Test::** Lymphocytes\_PX  
611

**Result::**

**Not Done::** NOT DONE

**Laboratory Normal Range:**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 14-Jan-2021 02:24

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX61 1	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Feb-11-2021 17:42:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - Audit Trail

**Form Version:** 20-Feb-2021 02:18

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (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 Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Lab Panel:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> HEMATOLOGY	Initial Entry

**3. Collection Date:**

Date	Location	User	Value	Reason
Feb-24-2021 17:06:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	Transcription Error
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry

**4. Specimen Type:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> BLOOD	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

**5.a**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def 1</b> <b>ined Identifi</b> <b>er:</b> <b>Test::</b> Hemogl obin_P X1 <b>Result::</b> 11.1 <b>Not Done::</b> <b>Lab Normal</b> <b>Range:</b>	Initial Entry

**5.a Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**5.a Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Hemoglobin_PX1	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

(b) (4), (b) (6)

**5.a Result:**

Date	Location	User	Value	Reason
Mar-05-2021 01:03:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:53:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal. this has been stated throughout audit trail multiple times. please do not constantly re-qery if same question has been addressed
Feb-25-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:	Result 11.1 is

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

10:46:05 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	Opened	present but lab normal range is missing. Kindly verify and update lab normal range (Low, High or unit) or else clarify. Thank you.
Feb-25-2021 08:42:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.
Feb-25-2021 03:40:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi (b) (4)	Query 1: Reissued: Opened	Result 11.1 is present but lab normal range is missing. Kindly verify and update lab normal range (Low, High or unit) or else clarify. Thank you.
Feb-24-2021 17:05:30 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)				records, only noted as abnormal.
Feb-24-2021 17:02:10 (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.
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 11.1	Initial Entry

**5.b**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Defined Identifier:</b> <b>Test::</b> Hemato crit_PX 2 <b>Result::</b> 32.6 <b>Not Done::</b> <b>Lab Normal Range:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.b Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (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
Feb-24-2021 17:02:10 (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
Mar-04-2021 23:16:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:53:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

				abnormal. this has been stated throughout audit trail multiple times. please do not constantly re-qery if same question has been addressed
Feb-25-2021 10:45:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Result 32.6 is present but lab normal range is missing. Kindly verify and update lab normal range
Feb-25-2021 08:42:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.
Feb-25-2021 03:41:49 (UTC-05:00)	ACV0PFEINFP6000	Sandip Namdeorao Suryawanshi	Query 1: Reissued: Opened	Result 32.6 is present but lab normal

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)		(b) (4)		range is missing. Kindly verify and update lab normal range (Low, High or unit) or else clarify. Thank you.
Feb-24-2021 17:05:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.
Feb-24-2021 17:02:10 (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.
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 32.6	Initial Entry

5.c

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def 3</b> <b>ined Identifier:</b> <b>Test::</b> Erythrocytes_PX 3 <b>Result::</b> <b>Not Done::</b> NOT DONE <b>Lab Normal Range:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.c Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**5.c Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Erythrocytes_PX3	Initial Entry

**5.c Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.d**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> Sponsor-Defi 5	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Test Identifier**

:

**Test::** Platelet  
s\_PX5

**Result::** 108

**Not Done::**

**Lab Normal**

**Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.d Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**5.d Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Platelets_PX5	Initial Entry

**5.d Result:**

Date	Location	User	Value	Reason
Mar-04-2021 23:16:02 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 12:53:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

				abnormal. this has been stated throughout audit trail multiple times. please do not constantly re-qery if same question has been addressed
Feb-25-2021 08:53:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thank you for your response. Kindly connect with your CRA for any further assistance if needed and update CRF as appropriate. Else clarify.
Feb-25-2021 08:41:19 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-25-2021 07:12:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Result 108 is present but lab normal range is missing. Kindly verify and update lab normal range (Low, High or unit) or else clarify. Thank you.
Feb-24-2021 17:05:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Reference ranges were not provided in the medical records, only noted as abnormal.
Feb-24-2021 17:02:10 (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.
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 108	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

5.e

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def 7</b> <b>ined Identifier:</b> <b>Test::</b> Leukoc ytes_P X7 <b>Result::</b> <b>Not Done::</b> NOT D ONE <b>Lab Normal</b> <b>Range:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 7	Initial Entry

**5.e Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Leukocytes_PX7	Initial Entry

**5.e Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.f**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-De</b> 608	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Identified Identifier:**

**Test::** Neutrop  
hils\_PX  
608

**Result::**

**Not Done::** NOT D  
ONE

**Lab Normal Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

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**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.f Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 608	Initial Entry

**5.f Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Neutrophils_PX608	Initial Entry

**5.f Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.g**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-De</b> 609	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Identified Identifier:**

**Test::** Eosinophils\_PX  
609

**Result::**

**Not Done::** NOT DONE

**Lab Normal Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.g Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 609	Initial Entry

**5.g Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Eosinophils_PX609	Initial Entry

**5.g Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.h**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-De</b> 612	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

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**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Identified Identifier:**

**Test::** Monocytes\_PX61  
2

**Result::**

**Not Done::** NOT DONE

**Lab Normal Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
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**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

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**5.h Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 612	Initial Entry

**5.h Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Monocytes_PX612	Initial Entry

**5.h Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.i**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-Def</b> 610 <b>ined Identifier:</b> <b>Test::</b> Basophi ls_PX61 0 <b>Result::</b> <b>Not Done::</b> NOT D ONE <b>Lab Normal Range:</b>	Initial Entry
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Version:** 20-Feb-2021 02:18

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.i Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 610	Initial Entry

**5.i Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Basophils_PX610	Initial Entry

**5.i Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

**5.j**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> <b>Sponsor-De</b> 611	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00)  
Eastern Time (US  
& Canada)

**Identified Identifier:**

**Test::** Lymphocytes\_PX  
611

**Result::**

**Not Done::** NOT DONE

**Laboratory Normal Range:**

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 20-Feb-2021 02:18

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** LOCAL LABORATORY DATA - REPEATING  
Hematology - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

**5.j Sponsor ID:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 611	Initial Entry

**5.j Test:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Lymphocytes_PX611	Initial Entry

**5.j Not Done:**

Date	Location	User	Value	Reason
Feb-24-2021 17:02:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT DONE	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 21-Aug-2020 02:50

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-24-2021 16:33:14 (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 Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date:**

Date	Location	User	Value	Reason
Feb-24-2021 16:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry
Feb-24-2021 16:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-05-2021 17:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier::</b> Not Applicable <b>Systolic::</b> 224 <b>Diastolic::</b> 70	New Information

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
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**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Respiratory Rate in respirations/minute:</b> 18 <b>Heart Rate in beats/minute:</b> 40	
Feb-24-2021 16:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable <b>Systolic:</b> 224 <b>Diastolic:</b> 70 <b>Respiratory Rate in respirations/minute:</b> 18 <b>Heart Rate in beats/minute:</b> 33	Initial Entry
Feb-24-2021 16:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable <b>Systolic:</b> <b>Diastolic:</b>	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

			<b>Respiratory Rate in respirations/minute:</b> <b>Heart Rate in beats/minute:</b>	
Dec-23-2020 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> Not Applicable <b>Systolic:</b> Not Applicable <b>Diastolic:</b> Not Applicable <b>Respiratory Rate in respirations/minute:</b> Not Applicable <b>Heart Rate in beats/minute:</b> Not Applicable	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Dec-23-2020 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
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**2.a Systolic:**

Date	Location	User	Value	Reason
Feb-26-2021 03:48:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 08:49:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is clinically related to the hospitalization for heart block.
Feb-25-2021 07:15:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM 1: Please clarify weather reported value is clinically significant or not. If yes update AE as appropriate or else clarify not clinically significant. Thank you.

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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
 Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
 History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 16:33:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-24-2021 16:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 224 is outside of Normal Range 90 - 140.
Feb-24-2021 16:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 224	Initial Entry
Feb-24-2021 16:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Feb-24-2021 16:33:14	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 70	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Feb-24-2021 16:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:07:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Feb-24-2021 16:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 18	Initial Entry
Feb-24-2021 16:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:07:10 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 21-Aug-2020 02:50

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Mar-05-2021 17:07:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 40	New Information
Feb-24-2021 16:33:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 33	Initial Entry
Feb-24-2021 16:31:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:07:10 (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 Dec/16/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 14-Jan-2021 02:17

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Mar-09-2021 15:36:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Feb-09-2021 16:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 14-Jan-2021 02:17

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. Date:**

Date	Location	User	Value	Reason
Feb-24-2021 16:58:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	Transcription Error
Feb-09-2021 16:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/28/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-09-2021 16:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Systolic:</b> 1 3 6 <b>Diastolic:</b> 5 8 <b>Respiratory Rate in respirations /minute:</b> 1 6	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 14-Jan-2021 02:17

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

			<b>Heart Rate in be 3 ats/minute:</b>	6
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**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-09-2021 16:39:44 (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
Feb-09-2021 16:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 136	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Feb-10-2021 13:17:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
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**Form Version:** 14-Jan-2021 02:17

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Feb-10-2021 10:42:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not clinically significant
Feb-09-2021 23:51:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued :Opened	DM: Confirmation on the out of range value as "clinically significant" or "not clinically significant" is expected as a response. Please review and confirm.
Feb-09-2021 16:40:51 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	reported hospital records
Feb-09-2021 16:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 58 is outside of Normal Range 60 - 90.
Feb-09-2021 16:39:44 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 58	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
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**Form Version:** 14-Jan-2021 02:17

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Eastern Time  
(US & Canada)

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Feb-09-2021 16:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 16	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Feb-09-2021 16:39:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 36	Initial Entry

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 20-Feb-2021 02:11

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-24-2021 16:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 20-Feb-2021 02:11

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - Audit Trail

**Form Version:** 20-Feb-2021 02:11

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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Date	Location	User	Value	Reason
Mar-05-2021 17:08:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Deleted	New Information
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
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**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
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**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date:**

Date	Location	User	Value	Reason
Mar-10-2021 05:34:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Mar-09-2021 15:37:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	log 2 has been deleted per query
Mar-09-2021 08:09:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 2: Opened	P21 Review- Requery 1- If this confirmed to be the abnormal value, kindly delete the log 2 as it is also collected on the same date. Kindly note if the vitals are collected on the same day only most abnormal value should be reported.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Mar-05-2021 07:40:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-04-2021 14:05:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirmed that value is the most abnormal of day
Mar-02-2021 02:37:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded. Please review all data entered on 18Dec2020 and remove as applicable. Else clarify.
Feb-24-2021 16:36:48 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

**2.a**

Date	Location	User	Value	Reason
Feb-24-2021 16:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier 1</b> : <b>Systolic::</b> 1 8 0 <b>Diastolic::</b> 6 6 <b>Respiratory Rate 1</b> <b>in respirations/m 8</b> <b>inute:</b> <b>Heart Rate in be 3</b> <b>ats/minute: 5</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-24-2021 16:36:48 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-26-2021 06:59:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	AE recorded
Feb-25-2021 08:50:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is clinically related to the hospitalization for heart block.
Feb-25-2021 07:16:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM 1: Please clarify weather reported value is clinically significant or not. If yes update AE as appropriate or else clarify not clinically significant. Thank you.
Feb-24-2021 16:37:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-24-2021 16:36:48 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 180 is outside of Normal Range 90 - 140.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)				
Feb-24-2021 16:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 180	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Feb-24-2021 16:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 66	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Feb-24-2021 16:36:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 18	Initial Entry

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Feb-24-2021 16:36:48 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 35	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date:**

Date	Location	User	Value	Reason
Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/19/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier 1</b> : <b>Systolic::</b> 1 6 8 <b>Diastolic::</b> 7 1 <b>Respiratory Rate 1</b> <b>in respirations/m 8</b> <b>inute:</b> <b>Heart Rate in be 7</b> <b>ats/minute: 1</b>	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry
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**2.a Systolic:**

Date	Location	User	Value	Reason
Feb-26-2021 08:52:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query.
Feb-25-2021 08:49:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is clinically related to the hospitalization for heart block.
Feb-25-2021 07:16:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM 1: Please clarify weather reported value is clinically significant or not. If yes update AE as appropriate or else clarify not clinically significant. Thank you.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
 Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
 History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 16:41:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 168 is outside of Normal Range 90 - 140.
Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 168	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 71	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 18	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

**2.a Heart Rate in beats/minute:**

Date	Location	User	Value	Reason
Feb-24-2021 16:40:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 71	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

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**1. Date:**

Date	Location	User	Value	Reason
Mar-08-2021 05:05:04 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Mar-05-2021 17:07:46 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	removing logline
Mar-05-2021 10:16:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Please note, this date is the same as the date on LINE 1. Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

				Please review all data entered on 17Dec2020 and remove as applicable. Else clarify
Mar-04-2021 14:05:33 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirmed that value is the most abnormal of day
Mar-02-2021 02:37:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded. Please review all data entered on 17Dec2020 and remove as applicable. Else clarify.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

Form: VITAL SIGNS - COVID - eCRF Audit Trail  
History

Form Version: 20-Feb-2021 02:11

Form Status: Data Complete, Deleted

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry
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2.a

Date	Location	User	Value	Reason
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier 1</b> : <b>Systolic::</b> 1 8 6 <b>Diastolic::</b> 5 3 <b>Respiratory Rate 1</b> <b>in respirations/m 7</b> <b>inute:</b> <b>Heart Rate in be 4</b> <b>ats/minute: 0</b>	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

& Canada)

**2.a Systolic:**

Date	Location	User	Value	Reason
Feb-26-2021 05:50:01 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 08:47:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is clinically related to the hospitalization for Heart Block.
Feb-25-2021 07:16:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM 1: Please clarify weather reported value is clinically significant or not. If yes update AE as appropriate or else clarify not clinically significant. Thank you.
Feb-24-2021 16:55:53 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Eastern Time (US & Canada)				
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Systolic BP 186 is outside of Normal Range 90 - 140.
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 186	Initial Entry

**2.a Diastolic:**

Date	Location	User	Value	Reason
Feb-26-2021 05:49:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-25-2021 08:46:24 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is clinically related to the hospitalization for the heart block.
Feb-25-2021 07:01:52	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Kindly confirm the

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History**Form Version:** 20-Feb-2021 02:11**Form Status:** Data Complete, Deleted**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

(UTC-05:00) Eastern Time (US & Canada)				Diastolic BP 53 recorded is clinically significant or not, thank you.
Feb-24-2021 16:56:06 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Diastolic BP 53 is outside of Normal Range 60 - 90.
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 53	Initial Entry

**2.a Respiratory Rate in respirations/minute:**

Date	Location	User	Value	Reason
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 17	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - COVID - eCRF Audit Trail  
History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

*2.a Heart Rate in beats/minute:*

Date	Location	User	Value	Reason
Feb-24-2021 16:55:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 40	Initial Entry

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit  
Trail

**Form Version:** 21-Aug-2020 02:51

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-24-2021 16:34:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date:**

Date	Location	User	Value	Reason
Feb-24-2021 16:34:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry
Feb-24-2021 16:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Mar-05-2021 07:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id Not Ap entifier:: plicable</b> <b>Oxygen S 99.0</b> <b>aturation</b> :	New Information

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History**Form Version:** 21-Aug-2020 02:51**Form Status:** Data Complete**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 16:34:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id Not Ap entifier::</b> plicable <b>Oxygen S aturation</b> :	Initial Entry
Feb-24-2021 16:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id Not Ap entifier::</b> plicable <b>Oxygen S aturation</b> :	Initial Entry
Dec-23-2020 12:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Id Not Ap entifier::</b> plicable <b>Oxygen S Not Ap aturation</b> plicable :	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Dec-23-2020 12:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2.a SPO2 Pulse Oximetry %**

Date	Location	User	Value	Reason
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 21-Aug-2020 02:51

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Mar-05-2021 07:05:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.0	New Information
Feb-24-2021 16:34:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 98.0	Initial Entry
Feb-24-2021 16:34:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:07:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit  
Trail

**Form Version:** 14-Jan-2021 02:17

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-09-2021 16:42:17 (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 Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 14-Jan-2021 02:17

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

[Back to Form](#)

**1. Date:**

Date	Location	User	Value	Reason
Feb-09-2021 16:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/28/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-09-2021 16:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> <b>Oxygen Saturation:</b> 97.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-09-2021 16:42:17 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 14-Jan-2021 02:17

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-09-2021 16:42:17 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 97.0	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit  
Trail

**Form Version:** 20-Feb-2021 02:11

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-24-2021 16:41:30 (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 Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit  
Trail

**Form Version:** 20-Feb-2021 02:11

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)

Date	Location	User	Value	Reason
Mar-05-2021 07:06:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	removed per query
Feb-24-2021 16:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

Form Version: 20-Feb-2021 02:11

Form Status: Data Complete

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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**1. Date:**

Date	Location	User	Value	Reason
Feb-24-2021 16:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/19/2020	Initial Entry

**2.a**

Date	Location	User	Value	Reason
Feb-24-2021 16:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 <b>Oxygen Saturation:</b> 93.0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-24-2021 16:41:30 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 16:41:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 93.0	Initial Entry
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**Header Text:** c4591001**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History**Form Version:** 20-Feb-2021 02:11**Form Status:** Incomplete, Data Complete, Deleted**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

[Back to Form](#)**1. Date:**

Date	Location	User	Value	Reason
Mar-05-2021 10:30:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	data deleted
Mar-05-2021 07:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	removing per query.
Mar-05-2021 07:05:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	removing per query.
Mar-05-2021 05:32:35 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	Please review all data entered on 17Dec2020 and remove as applicable. Else clarify
Mar-04-2021 14:05:11	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirmed that value is the

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Incomplete, Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

(UTC-05:00) Eastern Time (US & Canada)				most abnormal of day
Mar-02-2021 02:42:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Saumitra Dubey (b) (4)	Query 1: Opened	Per completion guidelines, If multiple values were recorded on a single day, the most abnormal should be recorded, i.e. the lowest Oxygen Saturation for the day. Please review all data entered on 17Dec2020 and remove as applicable. Else clarify.
Feb-24-2021 16:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry

2.a

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Incomplete, Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Date	Location	User	Value	Reason
Mar-05-2021 07:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifier:</b> 1 : <b>Oxygen Saturatio</b> <b>n:</b>	removed per query
Feb-24-2021 16:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> <b>Record Identifi</b> 1 <b>er::</b> <b>Oxygen Saturat</b> 99. <b>ion:</b> 0	Initial Entry

**2.a Record Identifier:**

Date	Location	User	Value	Reason
Feb-24-2021 16:55:41 (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
Mar-05-2021 07:06:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	removed per query

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF  
Audit Trail History

**Form Version:** 20-Feb-2021 02:11

**Form Status:** Incomplete, Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\*

Feb-24-2021 16:55:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 99.0	Initial Entry
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**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 06-Jul-2020 21:52

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** OXYGENATION PARAMETERS - eCRF Audit  
Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date Time of Assessment:**

Date	Location	User	Value	Reason
Dec-23-2020 12:07:49 (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
Dec-23-2020 12:07:49 (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
Dec-23-2020 12:07:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form Version:** 06-Jul-2020 21:55

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. What is the medication identifier?**

Date	Location	User	Value	Reason
Dec-23-2020 12:08:20 (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
Dec-23-2020 12:08:20 (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
Dec-23-2020 12:08:20 (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*

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** CONCOMITANT MEDICATIONS -  
VASOPRESSORS - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:55

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

*name is unknown, enter the full trade or proprietary name. Include clarifying information in the Medication text (e.g., Ingredient(s), route, use, formulation).*

Date	Location	User	Value	Reason
Dec-23-2020 12:08:20 (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
Dec-23-2020 12:08:20 (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
Dec-23-2020 12:08:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** IMAGING - Audit Trail

**Form Version:** 06-Jul-2020 21:53

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-24-2021 17:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** IMAGING - Audit Trail

**Form Version:** 06-Jul-2020 21:53

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-24-2021 17:23:21 (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 Dec/16/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-24-2021 17:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry
Feb-24-2021 17:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:05:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Feb-24-2021 17:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CHEST	Initial Entry
Feb-24-2021 17:18:12	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Dec-23-2020 12:05:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Feb-24-2021 17:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> X-RAY	Initial Entry
Feb-24-2021 17:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:05:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 17:21:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  Mild cardiomegaly. Mild vascular congestion and interstitial edema is questioned. No focal lung consolidation, pleural fluid or pneumothorax.	Initial Entry
Feb-24-2021 17:18:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b>	Initial Entry
Dec-23-2020 12:05:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> Not Applicable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Assessment:**

Date	Location	User	Value	Reason
Feb-24-2021 17:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020	Initial Entry

**2. Location of Assessment:**

Date	Location	User	Value	Reason
Feb-24-2021 17:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> HEAD	Initial Entry

**3. Type of Imaging Exam:**

Date	Location	User	Value	Reason
Feb-24-2021 17:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> CT SCAN	Initial Entry

**4. Assessment:**

Date	Location	User	Value	Reason
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 1 -  
Unscheduled Visit on Dec/16/2020

**Form:** IMAGING - eCRF Audit Trail History

**Form Version:** 06-Jul-2020 21:53

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-24-2021 17:23:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ABNORMAL <i>If abnormal, specify findings:</i>  No acute intracranial process. Mild atrophy and chronic small vessel ischemic changes.	Initial Entry
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Mar-01-2021 12:59:42 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Deleted	Query is invalid or does not apply
Mar-01-2021 12:59:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 3: Deleted	No other forms triggered.
Mar-01-2021 12:58:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Deleted	Query is invalid or does not apply
Feb-24-2021 16:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Candidate	Erroneous Visit is marked, but date of visit is entered. Please either untick the erroneous visit button if visit occurred, or mark any forms

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

				containing data within this visit as Not Done/Not Applicable at the form level.
Feb-24-2021 16:35:43 (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.
Feb-24-2021 16:35:43 (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.
Feb-24-2021 16:35:43 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/18/2020	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_ILL 2 -  
Unscheduled Visit on Dec/18/2020

**Form:** DATE OF VISIT - ILLNESS ONSET - eCRF  
Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)

**2. Erroneous Visit**

Date	Location	User	Value	Reason
Feb-24-2021 16:36:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ERRONEOUS VISIT	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Feb-24-2021 16:35:43 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> COVID_B	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/26/2021

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** DATE OF VISIT - ILLNESS CONVALESCENT -  
eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Visit**

Date	Location	User	Value	Reason
Jan-26-2021 16:10:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/26/2021	Initial Entry

**3. COVID-19 Illness Visit:**

Date	Location	User	Value	Reason
Jan-26-2021 16:10:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COVID_A1	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/26/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Data Origin**

Date	Location	User	Value	Reason
Jan-26-2021 16:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> SITE	Initial Entry

**2. Sample Type**

Date	Location	User	Value	Reason
Jan-26-2021 16:11:09 (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-27-2021 08:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Jan-26-2021 16:11:09 (UTC-05:00)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/26/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				no barcodes are entered. Please review and correct as appropriate.
Jan-26-2021 16:11:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Date of Collection : Jan/26/2021	Initial Entry

**5.a**

Date	Location	User	Value	Reason
Jan-27-2021 08:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Sample ID BR0F9 : F	Initial Entry

**5.a Sample ID**

Date	Location	User	Value	Reason
Jan-27-2021 08:58:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BR0F9F	Initial Entry

**5.b**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/26/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Jan-27-2021 08:59:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample I</b> BS7XW <b>D:</b> 8	Initial Entry

**5.b Sample ID**

Date	Location	User	Value	Reason
Jan-27-2021 08:59:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> BS7XW8	Initial Entry

**5.c**

Date	Location	User	Value	Reason
Jan-27-2021 08:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Entry:</b> <b>Sample I</b> BS7XW <b>D:</b> 9	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** POT\_COVID\_CONVA 1 -  
Unscheduled Visit on Jan/26/2021

**Form Version:** 22-Apr-2020 21:03

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** ELECTRONIC SAMPLE TRACKING -  
IMMUNOGENICITY - eCRF Audit Trail History

**Form Status:** Data Complete, Frozen, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

*5.c Sample ID*

Date	Location	User	Value	Reason
Jan-27-2021 08:59:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> BS7XW9	Initial Entry

**Header Text:** c4591001

**Visit:** End of Treatment - Unscheduled **Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History

**Form Version:** 15-Sep-2020 21:55 **Form Status:** Data Complete, Locked, Frozen, Verified

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-03-2020 15:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Nov/3/2020	Initial Entry

**2. Phase of Disposition:**

Date	Location	User	Value	Reason
Nov-03-2020 15:18:26 (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
Nov-03-2020 15:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> COMPLETED	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

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Date	Location	User	Value	Reason
Feb-11-2021 18:00:29 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Feb-11-2021 17:59:48 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	New Information
Feb-10-2021 10:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Feb-10-2021 10:38:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Undeleted	New Information
Feb-09-2021 16:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Deleted	New Information
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

& Canada)				
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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - Audit Trail

**Form Version:** 22-Apr-2020 21:02

**Form Status:**

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Category:**

Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 1	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-13-2021 07:59:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	SAE escalated to CRA.
Feb-05-2021 14:14:50	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	non was found

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Feb-02-2021 19:44:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Per report, findings during hospital stay suggest additional/possible Congestive heart failure/diastolic dysfunction. Pls advise if there were additional diagnosis made on discharge. thanks
Jan-27-2021 17:03:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	working on it to update soon
Jan-24-2021 21:07:11 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Jan-24-2021 10:33:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Response does not satisfy query.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Jan-22-2021 13:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Jan-22-2021 13:06:22 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> complete heart block	New Information
Jan-21-2021 03:36:41 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	SAE RECON:AER#2020511089, the term in SDB was updated to 'complete heart block' while retained as Bradycardia in AE CRF. Please confirm correct term. If safety update is required, please submit a follow-up form.
Jan-19-2021 14:19:25 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This will be updated soon
Jan-14-2021 18:21:14 (UTC-05:00)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Thanks for the response, no updates have been noted.

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** Logs - Unscheduled**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:02**Form Status:** Data Complete, Frozen**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)				
Jan-07-2021 10:57:09 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Answered	This will be updated soon. Have many more AE's and medications to update
Jan-06-2021 18:31:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Clinical_ Per report, the subject was hospitalized 2 days. However, information on hospital course, workup/lab results (including Covid testing, ECG) is not described. Kindly provide information in a FU report. Thank you.
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	<b>Data Ent</b> <b>ry:</b> Bradycard ia	Initial Entry

**4. Start Date Time:**

Date	Location	User	Value	Reason
Mar-11-2021 00:45:05 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query

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(US & Canada)				
Mar-10-2021 14:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Mar-10-2021 14:07:56 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020 UNK: UNK	New Information
Mar-10-2021 06:56:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	SAE RECON: AER#2020511089 ,onset date was updated to 08Dec2020 in Safety database however, recorded as 17Dec2020 on AE CRF. Please confirm correct Onset Date. If safety update is required, please submit a follow-up SAE form.
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020 18:43	Initial Entry

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(US & Canada)

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/19/2020 UN K:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

7. Is the adverse event serious?

If Yes, NOTIFY PFIZER IMMEDIATELY.

Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Jan-05-2021	ACV0PFEINFP6000	auto query	Query 1: Deleted	Close Auto

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

20:51:57 (UTC-05:00) Eastern Time (US & Canada)		(autoquery)		Query
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE Bradycardia: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO Did this serious event require or prolonged hospitalization?	Initial Entry

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			YES	
			Did this serious event result in persistent or significant disability/incapacity?	
			NO	
			Is this serious event life threatening?	
			YES	
			Other medically important serious event	
			NO	

**8. Is this adverse event the result of a study Medication Error?***If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
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Feb-02-2021 19:40:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Closed	Thanks.
Jan-27-2021 17:03:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	working on it to update soon
Jan-24-2021 10:35:14 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Response does not satisfy query.
Jan-19-2021 14:19:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This will be updated soon
Jan-14-2021 18:28:59 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Reissued: Opened	Thanks for confirming. Please make every effort possible to obtain further information and respond to the query once additional information is

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				available.
Jan-07-2021 11:04:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This will be submitted
Jan-06-2021 18:39:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	Giselle Castillo (b) (4)	Query 1: Opened	Per report submitted to safety, "Medical history and con meds were not reported". However, there are multiple items recorded in the MedHx page of this CRF. Please verify Mhx and submit a FU form so additional information is added to SAE report. Thanks
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), t	Initial Entry

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**Generated By:** (b) (4)

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& Canada)			his event is due to:  OTHER  <i>If Other, specify</i> :  A-V conducti on block	
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (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
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Jan-05-2021	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	Initial Entry

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

13:32:16 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	YES	
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RES OLVED WITH SEQ UELAE	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Jan-05-2021 13:32:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**15. Serious Adverse Event Number: For Pfizer Use Only**

Date	Location	User	Value	Reason
Jan-05-2021 20:51:57 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2020511089	Initial Entry

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**Form Status:** Data Complete, Frozen

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**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Category:**

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (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-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypokalemia	Initial Entry

**4. Start Date Time:**

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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/18/2020 UN K:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

***If Yes, NOTIFY PFIZER IMMEDIATELY.***

***Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important***

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**Subject Initials:** ---

**Generated By:** (b) (4)

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*medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-25-2021 10:47:30 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-25-2021 08:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Changed Information

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)				
Feb-25-2021 08:43:52 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to s tudy treatment(s), this event is due t o:  CONCOMITAN T DRUG TREA TMENT	Changed Information
Feb-24-2021 19:17:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	clinical: advised by CRA that causality was ConMed of furosemide. If this is correct, please update CRF. Thanks
Feb-23-2021 11:28:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical: last query issued in error
Feb-18-2021 17:09:55 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	clinical: Thanks, when discuss with PI, pls advise which medication

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**Subject Initials:** ---

**Generated By:** (b) (4)

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				was involved.
Feb-18-2021 17:01:49 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Confirming if the correct option was selected on our AE log with the physician. Updates will be made if required.
Feb-12-2021 14:02:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	clinical: pls advise if update available. Thanks
Feb-09-2021 16:33:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	waiting on site physician to update
Feb-09-2021 11:49:15 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	clinical: pls advise if update available. Thanks
Feb-05-2021 14:12:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	waiting on site physician to update

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**Generated By:** (b) (4)

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Feb-04-2021 09:57:08 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise what non-drug treatment caused AE. Thanks
Feb-02-2021 11:55:44 (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:  CONCOMITANT NON-DRUG TREATMENT	Initial Entry

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (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
Feb-02-2021 12:19:03 (UTC-05:00)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Eastern Time (US & Canada)

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Feb-02-2021 11:55:44 (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-02-2021 11:55:44 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**1. Category:**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 3	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> symptomatic bradyca rdia	Initial Entry

**4. Start Date Time:**

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**Generated By:** (b) (4)

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Date	Location	User	Value	Reason
Mar-05-2021 17:09:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/8/2020 UNK:U NK	New Information
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/6/2020 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/19/2020 UN K:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

**If Yes, record the type of medication error on the Medication Error Log.**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to st udy treatment(s), thi	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Generated Time (GMT):** 29-Mar-2021 11:34

& Canada)			s event is due to:	
			OTHER	
			<i>If Other, specify:</i>	
			complete heart block	

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (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
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

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**Site No:** 1131

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**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RES OLVED	Initial Entry

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-02-2021 12:00:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

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**Site No:** 1131

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Category:**

Date	Location	User	Value	Reason
Feb-03-2021 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-02-2021 12:04:36 (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-03-2021 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b>	Transcription Error
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 4	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

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3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Feb-12-2021 01:41:00 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	data deleted
Feb-11-2021 18:00:13 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	data deleted
Feb-11-2021 06:34:45 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued: Opened	Please consider deleting the logline if there is no data to be reported for this line. To delete the log entries, go in the Log Summary page and select the 'Delete' option at the bottom left of the screen and click 'Apply'.
Feb-10-2021	ACV0PFEINFP6000	(b) (6)	Query 2: Answer	cra instructed us

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**Header Text:** c4591001

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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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10:39:04 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	ed	to delete information
Feb-10-2021 06:44:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Not Applicable is not the valid response. If this data added in error then consider to delete this log line or else clarify. Thank you.
Feb-09-2021 21:12:31 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	CRA working with site to remove entry
Feb-09-2021 16:31:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	New Information
Feb-07-2021 23:22:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM: Not Applicable is not the valid response. If this data added in

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**Header Text:** c4591001

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**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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				error then consider to delete this log line or else clarify. Thank you.
Feb-05-2021 14:13:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	data updated
Feb-05-2021 14:13:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	data updated
Feb-05-2021 14:13:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Not Applicable	Initial Entry
Feb-04-2021 09:35:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	CLINQUERY2 - Thank you for your response. Please ensure all fields are removed accordingly.
Feb-04-2021	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM: Please

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**Header Text:** c4591001

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**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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01:55:29 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		complete this item or else clarify. Thank you.
Feb-03-2021 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Feb-03-2021 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b>	Transcription Error
Feb-03-2021 12:10:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY - COMPLETE HEART BLOCK is reported twice (AE1 & AE4). Please remove duplicate entry.
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> complete heart block	Initial Entry

**4. Start Date Time:**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**\*\*\* THIS REPEATING FORM HAS BEEN DELETED \*\*\***

Date	Location	User	Value	Reason
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020 18:43	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/19/2020 UN K:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 4	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization;**

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**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete, Deleted

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

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*Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Feb-03-2021 16:34:03 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-03-2021 05:43:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-02-2021 12:17:34 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Is this serious event associated with congenital anomaly or birth defect?  NO Did this serious event result in death?  NO Did this serious ev	New Information

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**Header Text:** c4591001

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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			<p>ent require or prolonged hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	
Feb-02-2021 12:17:10 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	data updated
Feb-02-2021	ACV0PFEINFP6000	(b) (6)	<b>Data Entry:</b>	New

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**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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<p>12:16:49 (UTC-05:00) Eastern Time (US &amp; Canada)</p>		<p>(b) (4), (b) (6)</p>	<p>YES</p> <p>Is this serious event associated with congenital anomaly or birth defect?</p> <p>NO</p> <p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Is this serious event life threatening?</p> <p>YES</p> <p>Other medically important serious event</p> <p>YES</p>	<p>Information</p>
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**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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<p>Feb-02-2021 12:15:42 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> YES Did this serious event require or prolong hospitalization?  YES Is this serious event life threatening?  YES Other medically important serious event  YES</p>	<p>New Information</p>
<p>Feb-02-2021 12:12:45 (UTC-05:00) Eastern Time (US &amp; Canada)</p>	<p>ACV0PFEINFP6000</p>	<p>(b) (4), (b) (6)</p>	<p><b>Data Entry:</b> YES Did this serious event require or prolong hospitalization?  YES Is this serious event life threatening?</p>	<p>New Information</p>

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**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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			YES	
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Is this adverse event serious?' is reported 'Yes', but at least one seriousness criteria is missing. Please review and update as appropriate.
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE complete heart block: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES Did this serious event require or prolong hospitalization?	Initial Entry

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			YES	
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8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to study treatment(s), this event is due to:  OTHER  <i>If Other, specify:</i>  av conduction block	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT APPLICABLE	Initial Entry
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**11. Was a Concomitant Medication given?**

Date	Location	User	Value	Reason
Feb-02-2021 12:04:36 (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
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	Initial Entry

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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& Canada)

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-02-2021 12:04:36 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

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**Generated By:** (b) (4)

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**1. Category:**

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 5	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> hypertensive urgency	Initial Entry

**4. Start Date Time:**

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**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO End Date Time:  Dec/19/2020 UN K:UNK	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 2	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**

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

*medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).*

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**  
*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-18-2021 17:07:27 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 16:42:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per AE source.

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Header Text: c4591001

Visit: Logs - Unscheduled

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen

Site No: 1131

Site Name: (1131) PriMED Clinical Research

Subject No: 11311151

Subject Initials: ---

Generated By: (b) (4)

Generated Time (GMT): 29-Mar-2021 11:34

& Canada)				
Feb-18-2021 16:42:50 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RELATED If Not Related to s tudy treatment(s), this event is due to :  OTHER  <i>If Other, specif y:</i>  Heart Block	updated per AE source.
Feb-12-2021 14:03:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	clinical: pls advise if update available. Thanks
Feb-09-2021 16:34:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	waiting on site physician to update
Feb-09-2021 11:50:20 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	clinical: pls advise if update available. Thanks
Feb-05-2021 17:24:12	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	this will be updated soon

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)		
Feb-05-2021 14:46:21 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	clinical: pls clarify. Heart block is not a non-drug treatment. If heart block was the causality pls enter as such. Pls also explain how heart block was the cause of hypertensive urgency. Thanks
Feb-05-2021 14:02:40 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	heart block
Feb-04-2021 09:57:32 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	clinical: pls advise what non-drug treatment caused AE. Thanks

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-02-2021 12:08:12 (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 :  CONCOMITANT NON-DRUG TREATMENT	Initial Entry
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**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (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
Feb-02-2021 12:08:12 (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
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090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry
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**13. What was the outcome of this adverse event?:**

Date	Location	User	Value	Reason
Feb-02-2021 17:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Feb-02-2021 17:01:58 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERED/RESOLVED	New Information
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	For AE hypertensive urgency: Response to "What was the outcome of this adverse event?" is 'Recovering/Resolving' but AE End Date/Time is present.
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> RECOVERING/RESOLVING	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete, Frozen

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-02-2021 12:08:12 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Category:**

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ADVERSE EVENT	Initial Entry

**2. AE ID:**

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> 6	Initial Entry

**3. Adverse Event:**

*(If possible specify diagnosis, not individual symptoms)*

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> mild cardiomegaly	Initial Entry

**4. Start Date Time:**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Dec/17/2020 UNK:U NK	Initial Entry

**5. Is the adverse event still ongoing?**

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> YES	Initial Entry

**6. Toxicity Grade:**

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> 1	Initial Entry

**7. Is the adverse event serious?**

**If Yes, NOTIFY PFIZER IMMEDIATELY.**

**Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to**

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

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**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

*prevent above outcomes).*

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**8. Is this adverse event the result of a study Medication Error?**

*If Yes, record the type of medication error on the Medication Error Log.*

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**9. Is this event related to study treatment:**

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (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:  CONCOMITANT NON-DRUG TREATMENT	Initial Entry

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**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

**10. Latest Action Taken with Study Treatment:**

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (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
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

**12. Was a Non-Drug Treatment given?**

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (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
Feb-02-2021 17:05:39	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NOT RECOVERED/	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Logs - Unscheduled

**Form:** ADVERSE EVENT REPORT - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:02

**Form Status:** Data Complete

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	NOT RESOLVED	
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**14. Did the adverse event cause the subject to be discontinued from the study?**

Date	Location	User	Value	Reason
Feb-02-2021 17:05:39 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> NO	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** DATE OF VISIT - eCRF Audit Trail History  
Unscheduled

**Form Version:** 22-Apr-2020 21:02      **Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131      **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151      **Subject Initials:** ---

**Generated By:** (b) (4)      **Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Date of Visit*

Date	Location	User	Value	Reason
Jan-27-2021 13:23:05 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Potential ReVax Initial Contact - **Form:** FURTHER VACCINATION CONFIRMATION -  
Unscheduled eCRF Audit Trail History

**Form Version:** 10-Dec-2020 02:25 **Form Status:** Data Complete, Frozen

**Site No:** 1131 **Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151 **Subject Initials:** ---

**Generated By:** (b) (4) **Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Select appropriate response - Is participant willing to return for Vaccination 3?*

Date	Location	User	Value	Reason
Jan-27-2021 13:23:16 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Participant is willing to return for Vaccinat ion 3 Participant is:  eligible and NOT confirmed to have received only plac ebo at Vaccinatio n 1/2	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001

**Visit:** Disposition - Unscheduled

**Form:** TREATMENT UNBLINDED - eCRF Audit Trail History

**Form Version:** 22-Apr-2020 21:03

**Form Status:** Data Complete, Frozen, Verified

**Site No:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

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**1. Date Treatment Unblinded :**

Date	Location	User	Value	Reason
Jan-27-2021 13:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Jan/18/2021	Initial Entry

**2. Primary Reason for Unblinding:**

Date	Location	User	Value	Reason
Jan-27-2021 13:22:38 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> ASSESS ELIGIBILI TY FOR ADDITIO NAL VACCINATIO N	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)

**Header Text:** c4591001**Visit:** Subject Status - Unscheduled**Form:** SUBJECT STATUS - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Verified**Site No:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34[Back to Form](#)**1. Subject Status**

Date	Location	User	Value	Reason
Nov-03-2020 15:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> FOLLOW-UP	Initial Entry
Sep-09-2020 10:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entry:</b> ENROLLED/RANDOMIZED	Initial Entry
Sep-08-2020 20:51:34 (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
Jan-05-2021 20:52:47 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Jan-05-2021	ACV0PFEINFP6000	(b) (6)	Query 1: A	This has been updated

**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:** 1131**Site Name:** (1131) PriMED Clinical Research**Subject No:** 11311151**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 11:34

13:32:51 (UTC-05:00) Eastern Time (US & Canada)		(b) (4), (b) (6)	answered	sorry for the delay
Jan-02-2021 05:33:07 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: O pened	SAE RECON:AER#2020511089 bradycardia(onset date:17Dec2020)was reported as serious in Safety database but missing in AE CRF. Please confirm and update CRF. If safety update is required, submit a follow-up SAE Form.
Nov-03-2020 15:18:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entr</b> <b>y:</b> Nov/3/202 0	Initial Entry
Sep-09-2020 10:44:26 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entr</b> <b>y:</b> Sep/8/2020	Initial Entry
Sep-08-2020 20:51:34 (UTC-05:00) Eastern Time	ACV0PFEINFP6000	auto calc (autocalc)	<b>Data Entr</b> <b>y:</b> Sep/8/2020	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:** 1131

**Site Name:** (1131) PriMED Clinical Research

**Subject No:** 11311151

**Subject Initials:** ---

**Generated By:** (b) (4)

**Generated Time (GMT):** 29-Mar-2021 11:34

(US & Canada)				
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**Header Text:** c4591001

**Visit:** Investigator Signature -  
Unscheduled

**Form Version:** 22-Apr-2020 21:04

**Site No:** 1131

**Subject No:** 11311151

**Generated By:** (b) (4)

**Form:** CASEBOOK SIGNATURE FORM - eCRF Audit  
Trail History

**Form Status:** Data Complete, Verified

**Site Name:** (1131) PriMED Clinical Research

**Subject Initials:** ---

**Generated Time (GMT):** 29-Mar-2021 11:34

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*1. Casebook Signature*

Date	Location	User	Value	Reason
Oct-16-2020 10:38:54 (UTC-05:00) Eastern Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<b>Data Entry:</b> Click Here to Enable	Initial Entry

090177e196ae3ea8\Final\Final On: 01-Apr-2021 04:57 (GMT)