

Header Text: c4591001

Visit: COHORT_SELECTION

Form: COHORT SELECTION

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Cohort Selection

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

1.	Select appropriate response - Protocol version	08 SEP 2020
2.	Select appropriate response - What cohort does the subject belong to?	STAGE 3 COHORTS

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent

1.	Consent Was:	OBTAINED Date Written Consent Obtained Sep/21/2020
----	--------------	--

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Demography

1.	Subject ID	[10471252]
2.	Birth Date:	(b) (6) 1957
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:	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Sep/21/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Form Comments

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DISPOSITION - SCREENING

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening

1.	Date of Completion/Discontinuation /Death	Sep/21/2020
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: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Medical History Details

1.a	Line/MH Number:	[1]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[diabetes type II]
	Start Date:	UNK/UNK/2010
	Ongoing:	YES
1.b	Line/MH Number:	[2]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[atrial fibrillation]
	Start Date:	UNK/UNK/2012
	Ongoing:	YES
1.c	Line/MH Number:	[3]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[gallstones]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.d	Line/MH Number:	[4]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[torn rotator cuff (right)]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

1.e	Line/MH Number:	[5]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral broken ankles]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.f	Line/MH Number:	[6]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[ace inhibitor allergy]
	Start Date:	UNK/UNK/2015
	Ongoing:	YES
1.g	Line/MH Number:	[7]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[cholecystectomy]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010
1.h	Line/MH Number:	[8]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[rotator cuff repair (right)]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

1.i	Line/MH Number:	[9]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[left knee replacement]
	Start Date:	UNK/UNK/2015
	Ongoing:	NO End Date: UNK/UNK/2015
1.j	Line/MH Number:	[10]
	Disease/Syndrome/Surgery /Non-Drug Allergies/Drug Allergies:	[bilateral fused ankles]
	Start Date:	UNK/UNK/2010
	Ongoing:	NO End Date: UNK/UNK/2010

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: HIV STATUS

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

HIV Status

1.	Select appropriate response - What is the subject HIV status?	The subject is NOT known to be HIV POSITIVE
----	---	---

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Sep/21/2020
2.	Weight:	[245.0]
3.	Unit:	LB
4.	Height:	[73.0]
5.	Unit:	in
6.	Body Mass Index:	[32.3]

Vital Signs Details

7.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: RANDOMIZATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition

1.	Randomization Date :	Sep/21/2020
2.	Randomization Number:	[262745]
3.	Randomization Group:	[]

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
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	[BM950F]
5.b	Sample ID	[BM950G]
5.c	Sample ID	[BM950H]
5.d	Sample ID	[BK8YTL]
5.e	Sample ID	[BK8YTM]

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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Sep/21/2020
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	[BM94ZF]
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Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BLINDED THERAPY]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Sep/21/2020 14:10
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

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: REACTOGENICITY DIARY

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Reactogenicity Diary

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

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Nov/13/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vital Signs

1.	Date:	Nov/13/2020
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Vital Signs Details

2.a	Record Identifier:	1
	Temperature:	[97.5]
	Unit:	F
	Temperature Location:	FOREHEAD

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Nov/13/2020
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	[BPSXTZ]
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Form Comments](#)

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	Not Applicable _____	Comments
2.	Treatment Name	Not Applicable _____ []	Comments
3.	Formulation:	Not Applicable _____	Comments
4.	Dose Date Time:	Not Applicable _____ //	Comments
5.	Anatomical Location:	Not Applicable _____	Comments
6.	Body Side:	Not Applicable _____	Comments
7.	Route:	Not Applicable _____	Comments
8.	Actual Dose:	Not Applicable _____ []	Comments
9.	Unit:	Not Applicable _____	Comments
10.	Timeframe Subject Was Observed	Not Applicable _____	Comments
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	Not Applicable _____	Comments

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Dec/11/2020
2.	Erroneous Visit	

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Dec/11/2020
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	[BJYB47]
5.b	Sample ID	[BPSY40]
5.c	Sample ID	[BPSY3Z]
5.d	Sample ID	[BPSY3Y]

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET
Oct/14/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Oct/14/2020
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 Oct/14/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Signs and Symptoms

1.	Date of Assessment:	Oct/14/2020
2.	Date of First Symptom Started:	Oct/12/2020
3.	Symptoms Ongoing?	NO Date of Last Symptom Resolved: Nov/15/2020

Symptoms

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

Symptoms - Other

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19
Oct/14/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Symptoms - Other Text:

[Headache]

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: MICROBIOLOGY SPECIMEN

Form Version: 06-Jul-2020 21:54

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	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	Repeating Pages

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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[Form Comments](#)

[eCRF Audit Trail History](#)

[Form Audit Trail](#)

Microbiology Specimen

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

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF
Oct/14/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB_SELF
3.	Sample Collected?	YES Date of Collection: Oct/14/2020
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	[CV46611]
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB
Oct/14/2020

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION
Oct/14/2020**Form Version:** 10-Oct-2020 15:59**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[eCRF Audit Trail History](#)**Health Care Utilization**

1.a	Physician or Healthcare Professional:	SPECIALIST
	Occurrence of Visits or Contacts:	NO
1.b	Physician or Healthcare Professional:	EMERGENCY ROOM
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]
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
1.f	Physician or Healthcare Professional:	OTHER
	Occurrence of Visits or Contacts:	YES Number of Visits or Contacts: [1]

Health Care Utilization Other

2.	Other Type of Practitioner Specify:	[Covid Test Center/Regional hospital]
----	-------------------------------------	---------------------------------------

Health Care Utilization

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: HOSPITALIZATION DETAILS

Form Version: 22-Apr-2020 21:02

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Hospitalization Category	Hospitalization Term	Admission Date	Ongoing	Form Instance
1.	HOSPITALIZATION STATUS	HOSPITAL	Oct/16/2020	YES	Repeating Pages

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS

Oct/14/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Hospitalization Details

1.	Hospitalization Category:	HOSPITALIZATION STATUS
2.	Hospitalization Term:	HOSPITAL
3.	Admission Date:	Oct/16/2020
4.	Ongoing?	YES

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: RESPIRATORY TREATMENT

Form Version: 06-Jul-2020 21:53

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Treatment Identifier	Con Non-Drug Treatments Pre-specified	Treatment	Treatment	Start Date	Form Instance
1.	1	YES	HIGH FLOW OXYGEN THERAPY	HIGH FLOW OXYGEN THERAPY	Oct/16/2020	Repeating Pages

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT

Oct/14/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Respiratory Treatment

1.	What is the treatment Identifier?	[1]
2.	Concomitant Non-drug Treatment Pre-specified:	YES
3.	Treatment:	HIGH FLOW OXYGEN THERAPY
4.	Treatment:	[HIGH FLOW OXYGEN THERAPY]
5.	Start Date:	Oct/16/2020
6.	Ongoing?	YES

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS
Oct/14/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Illness Details

1.	Category of Clinical Event:	POTENTIAL COVID-19 ILLNESS
2.	Was a diagnosis obtained for Potential COVID-19 Illness?	YES Respiratory Illness Diagnosis: [Covid-19] Date of Diagnosis: Oct/14/2020
3.	Toxicity Grade:	2

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: ILLNESS DETAILS - SEVERE

Form Version: 17-Jul-2020 21:55

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - SEVERE

Oct/14/2020

Form Version: 17-Jul-2020 21:55

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Illness Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 15-Sep-2020 21:51

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date:	Specimen Type	Lab Result			Form Instance
1.	CLINICAL CHEMISTRY	Huntsville Hospital 101 Sibley Ave Huntsville Alabama	Oct/17/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	C Reactive Protein_PX329	1.1	
					30	Alanine Aminotransferase_PX30	30	
					28	Aspartate Aminotransferase_PX28	52	
					35	Alkaline Phosphatase_PX35	73	
					21	Bilirubin_PX21	0.4	
					47	Blood Urea Nitrogen_PX47	30	
					48	Creatinine_PX48	1.3	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date	Specimen Type	Lab Result	Form Instance																								
2.	CLINICAL CHEMISTRY	Huntsville Hospital Systems 101 Sivley Avenue Huntsville, Alabama	Oct/16/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>[]</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>[]</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>[]</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>[]</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>[]</td> </tr> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>28</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>1.3</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	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	28	48	Creatinine_PX48	1.3	Repeating Pages
					Sponsor-Defined Identifier	Test:	Result:																							
					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	28																							
48	Creatinine_PX48	1.3																												
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	28																												
48	Creatinine_PX48	1.3																												
3.	CLINICAL CHEMISTRY	[]	Oct/18/2020	BLOOD	<table border="1"> <thead> <tr> <th>Sponsor-Defined Identifier</th> <th>Test:</th> <th>Result:</th> </tr> </thead> <tbody> <tr> <td>329</td> <td>C Reactive Protein_PX329</td> <td>[]</td> </tr> <tr> <td>30</td> <td>Alanine Aminotransferase_PX30</td> <td>38</td> </tr> <tr> <td>28</td> <td>Aspartate Aminotransferase_PX28</td> <td>20</td> </tr> <tr> <td>35</td> <td>Alkaline Phosphatase_PX35</td> <td>72</td> </tr> <tr> <td>21</td> <td>Bilirubin_PX21</td> <td>0.3</td> </tr> <tr> <td>47</td> <td>Blood Urea Nitrogen_PX47</td> <td>24</td> </tr> <tr> <td>48</td> <td>Creatinine_PX48</td> <td>1.0</td> </tr> </tbody> </table>	Sponsor-Defined Identifier	Test:	Result:	329	C Reactive Protein_PX329	[]	30	Alanine Aminotransferase_PX30	38	28	Aspartate Aminotransferase_PX28	20	35	Alkaline Phosphatase_PX35	72	21	Bilirubin_PX21	0.3	47	Blood Urea Nitrogen_PX47	24	48	Creatinine_PX48	1.0	Repeating Pages
					Sponsor-Defined Identifier	Test:	Result:																							
					329	C Reactive Protein_PX329	[]																							
					30	Alanine Aminotransferase_PX30	38																							
					28	Aspartate Aminotransferase_PX28	20																							
					35	Alkaline Phosphatase_PX35	72																							
					21	Bilirubin_PX21	0.3																							
					47	Blood Urea Nitrogen_PX47	24																							
48	Creatinine_PX48	1.0																												
329	C Reactive Protein_PX329	[]																												
30	Alanine Aminotransferase_PX30	38																												
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35	Alkaline Phosphatase_PX35	72																												
21	Bilirubin_PX21	0.3																												
47	Blood Urea Nitrogen_PX47	24																												
48	Creatinine_PX48	1.0																												

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Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY

Form Version: 10-Oct-2020 15:58

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Category for Lab Test	Vendor Name	Collection Date	Specimen Type	Lab Result			Form Instance
4.	CLINICAL CHEMISTRY	Huntsville Hospital Systems 101 Sivley Avenue Huntsville, Alabama	Oct/19/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	C Reactive Protein_PX329	[]	
					30	Alanine Aminotransferase_PX30	31	
					28	Aspartate Aminotransferase_PX28	17	
					35	Alkaline Phosphatase_PX35	67	
					21	Bilirubin_PX21	0.3	
					47	Blood Urea Nitrogen_PX47	29	
					48	Creatinine_PX48	0.8	
5.	CLINICAL CHEMISTRY	Huntsville Hospital 101 Sivley Huntsville AL 35801	Oct/23/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					329	C Reactive Protein_PX329	[]	
					30	Alanine Aminotransferase_PX30	33	
					28	Aspartate Aminotransferase_PX28	21	
					35	Alkaline Phosphatase_PX35	65	
					21	Bilirubin_PX21	.3	
					47	Blood Urea Nitrogen_PX47	25	
					48	Creatinine_PX48	0.9	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/14/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Huntsville Hospital 101 Sivley Ave Huntsville Alabama]
3.	Collection Date:	Oct/17/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]	
	Test:	C Reactive Protein_PX329	
	Result:	[1.1]	
	Not Done:		
	LNMT	Low [<0.5] High [<0.5] Unit mg/L	
5.b	Sponsor ID:	[30]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	[30]	Comments
	Not Done:		Comments
	LNMT	Low [<39] High [<39] Unit U/L	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/14/2020

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	[28]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	[52]	Comments
	Not Done:		Comments
	LNMT	Low [<42] High [<42] Unit U/L	Comments
5.d	Sponsor ID:	[35]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	[73]	Comments
	Not Done:		Comments
	LNMT	Low [39] High [170.4] Unit U/L	Comments
5.e	Sponsor ID:	[21]	
	Test:	Bilirubin_PX21	
	Result:	[0.4]	
	Not Done:		
	LNMT	Low [<1.0] High [<1.0] Unit mg/dL	

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[30]
	Not Done:	
	LNMT	Low [8] High [23] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[1.3]
	Not Done:	
	LNMT	Low [0.7] High [1.2] Unit mg/dL

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Huntsville Hospital Systems 101 Sivley Avenue Huntsville, Alabama]
3.	Collection Date:	Oct/16/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]
	Test:	C Reactive Protein_PX329
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/14/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[]
	Not Done:	NOT DONE
	LNMT	Low [] High [] Unit
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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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/14/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[28]
	Not Done:	
	LNMT	Low [8] High [23] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[1.3]
	Not Done:	
	LNMT	Low [0.7] High [1.2] Unit mg/dL

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/14/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[]
3.	Collection Date:	Oct/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	
5.b	Sponsor ID:	[30]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	[38]	Comments
	Not Done:		Comments
	LNMT	Low [<42] High [<42] Unit U/L	Comments

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/14/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	[28]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	[20]	Comments
	Not Done:		Comments
	LNMT	Low [<39] High [<39] Unit U/L	Comments
5.d	Sponsor ID:	[35]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	[72]	Comments
	Not Done:		Comments
	LNMT	Low [39] High [117] Unit U/L	Comments
5.e	Sponsor ID:	[21]	
	Test:	Bilirubin_PX21	
	Result:	[0.3]	
	Not Done:		
	LNMT	Low [<1.0] High [<1.0] Unit mg/dL	

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Subject No: 10471252

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Generated By: (b) (4)

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

5 f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[24]
	Not Done:	
	LNMT	Low [8] High [23] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[1.0]
	Not Done:	
	LNMT	Low [0.7] High [1.2] Unit mg/dL

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
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Form Version: 10-Oct-2020 15:58

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Huntsville Hospital Systems 101 Sivley Avenue Huntsville, Alabama]
3.	Collection Date:	Oct/19/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[329]	
	Test:	C Reactive Protein_PX329	
	Result:	[]	
	Not Done:	NOT DONE	
	LNMT	Low [] High [] Unit	
5.b	Sponsor ID:	[30]	Comments
	Test:	Alanine Aminotransferase_PX30	
	Result:	[31]	Comments
	Not Done:		Comments
	LNMT	Low [<42] High [<42] Unit U/L	Comments

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY
Oct/14/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.c	Sponsor ID:	[28]	Comments
	Test:	Aspartate Aminotransferase_PX28	
	Result:	[17]	Comments
	Not Done:		Comments
	LNMT	Low [<39] High [<39] Unit U/L	Comments
5.d	Sponsor ID:	[35]	Comments
	Test:	Alkaline Phosphatase_PX35	
	Result:	[67]	Comments
	Not Done:		Comments
	LNMT	Low [29] High [117] Unit U/L	Comments
5.e	Sponsor ID:	[21]	
	Test:	Bilirubin_PX21	
	Result:	[0.3]	
	Not Done:		
	LNMT	Low [<1.0] High [<1.0] Unit mg/dL	

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Oct/14/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

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5.f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[29]
	Not Done:	
	LNMT	Low [5] High [28] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.8]
	Not Done:	
	LNMT	Low [0.7] High [1.2] Unit mg/dL

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Oct/14/2020

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

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Lab Chemistry Details

1.	Lab Panel:	CLINICAL CHEMISTRY
2.	Laboratory Name and Address	[Huntsville Hospital 101 Sivley Huntsville AL 35801]
3.	Collection Date:	Oct/23/2020
4.	Specimen Type:	BLOOD

Lab Result

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

5.b	Sponsor ID:	[30]
	Test:	Alanine Aminotransferase_PX30
	Result:	[33]
	Not Done:	
	LNMT	Low [<42] High [<42] Unit U/L

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5.c	Sponsor ID:	[28]
	Test:	Aspartate Aminotransferase_PX28
	Result:	[21]
	Not Done:	
	LNMT	Low [<39] High [<39] Unit U/L
5.d	Sponsor ID:	[35]
	Test:	Alkaline Phosphatase_PX35
	Result:	[65]
	Not Done:	
	LNMT	Low [39] High [117] Unit U/L
5.e	Sponsor ID:	[21]
	Test:	Bilirubin_PX21
	Result:	[.3]
	Not Done:	
	LNMT	Low [<1.0] High [<1.0] Unit mg/dL

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5 f	Sponsor ID:	[47]
	Test:	Blood Urea Nitrogen_PX47
	Result:	[25]
	Not Done:	
	LNMT	Low [22] High [29] Unit mg/dL
5.g	Sponsor ID:	[48]
	Test:	Creatinine_PX48
	Result:	[0.9]
	Not Done:	
	LNMT	Low [0.7] High [1.2] Unit mg/dL

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Visit: POT_COVID_ILL 1

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Form Version: 15-Sep-2020 21:55

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
1.	HEMATOLOGY	Huntsville Hospital 101 Sivley Huntsville Alabama 35801	Oct/16/2020	BLOOD				Repeating Pages
					1	Hemoglobin_PX1	15.4	
					2	Hematocrit_PX2	43.7	
					3	Erythrocytes_PX3	5.27	
					5	Platelets_PX5	160	
					7	Leukocytes_PX7	4.63	
					608	Neutrophils_PX608	2.94	
					609	Eosinophils_PX609	0.0	
					612	Monocytes_PX612	0.48	
					610	Basophils_PX610	0.0	
					611	Lymphocytes_PX611	1.21	

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Form Version: 10-Oct-2020 16:02

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
2.	HEMATOLOGY	Huntsville Hospital 101 Sivilley Huntsville AL 35801	Oct/18/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	12.9	
					2	Hematocrit_PX2	36.7	
					3	Erythrocytes_PX3	4.34	
					5	Platelets_PX5	165	
					7	Leukocytes_PX7	4.45	
					608	Neutrophils_PX608	2.39	
					609	Eosinophils_PX609	0.00	
					612	Monocytes_PX612	0.45	
					610	Basophils_PX610	0.01	
					611	Lymphocytes_PX611	1.58	
3.	HEMATOLOGY	Huntsville Hospital 101 Sivilley Huntsville AL 35801	Oct/19/2020	BLOOD	Sponsor-Defined Identifier	Test:	Result:	Repeating Pages
					1	Hemoglobin_PX1	13.1	
					2	Hematocrit_PX2	37.0	
					3	Erythrocytes_PX3	4.31	
					5	Platelets_PX5	160	
					7	Leukocytes_PX7	4.63	
					608	Neutrophils_PX608	12.5	

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#	Category for Lab Test	Vendor Name (DERIVED)	Collection Date:	Specimen Type	Lab Result			Form Instance
					Sponsor-Defined Identifier	Test:	Result:	
					609	Eosinophils_PX609	0.00	
					612	Monocytes_PX612	0.48	
					610	Basophils_PX610	0.00	
					611	Lymphocytes_PX611	2.94	
4.	HEMATOLOGY	Huntsville Hospital 101 Sivy Huntsville AL 35801	Oct/20/2020	BLOOD	1	Hemoglobin_PX1	13.1	Repeating Pages
					2	Hematocrit_PX2	37.1	
					3	Erythrocytes_PX3	4.36	
					5	Platelets_PX5	172	
					7	Leukocytes_PX7	5.80	
					608	Neutrophils_PX608	3.35	
					609	Eosinophils_PX609	0.00	
					612	Monocytes_PX612	0.44	
					610	Basophils_PX610	0.02	
					611	Lymphocytes_PX611	1.86	

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Huntsville Hospital 101 Sivley Huntsville Alabama 35801]
3.	Collection Date:	Oct/16/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[15.4]
	Not Done:	
	LNMT	Low [12.2] High [16.7] Unit g/dL
5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[43.7]
	Not Done:	
	LNMT	Low [38.2] High [49.2] Unit %

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5.c	Sponsor ID:	[3]	
	Test:	Erythrocytes_PX3	
	Result:	[5.27]	
	Not Done:		
	LNMT	Low [4.40] High [5.50] Unit 10^6/cu mm	
5.d	Sponsor ID:	[5]	Comments
	Test:	Platelets_PX5	
	Result:	[160]	Comments
	Not Done:		Comments
	LNMT	Low [137] High [352] Unit 10^3/uL	Comments
5.e	Sponsor ID:	[7]	Comments
	Test:	Leukocytes_PX7	
	Result:	[4.63]	Comments
	Not Done:		Comments
	LNMT	Low [4.10] High [12.20] Unit 10^3/uL	Comments

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Subject Initials: ---

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5.f	Sponsor ID:	[608]	Comments
	Test:	Neutrophils_PX608	
	Result:	[2.94]	Comments
	Not Done:		Comments
	LNMT	Low [1.50] High [7.90] Unit 10^3/uL	Comments
5.g	Sponsor ID:	[609]	Comments
	Test:	Eosinophils_PX609	
	Result:	[0.0]	Comments
	Not Done:		Comments
	LNMT	Low [0.00] High [0.50] Unit 10^3/uL	Comments
5.h	Sponsor ID:	[612]	Comments
	Test:	Monocytes_PX612	
	Result:	[0.48]	Comments
	Not Done:		Comments
	LNMT	Low [0.30] High [1.10] Unit 10^3/uL	Comments

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5.i	Sponsor ID:	[610]	Comments
	Test:	Basophils_PX610	
	Result:	[0.0]	Comments
	Not Done:		Comments
	LNMT	Low [0.00] High [0.01] Unit 10^3/uL	Comments
5.j	Sponsor ID:	[611]	Comments
	Test:	Lymphocytes_PX611	
	Result:	[1.21]	Comments
	Not Done:		Comments
	LNMT	Low [1.10] High [3.40] Unit 10^3/uL	Comments

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Huntsville Hospital 101 Sivley Huntsville AL 35801]
3.	Collection Date:	Oct/18/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[12.9]
	Not Done:	
	LNMT	Low [12.2] High [16.7] Unit g/dL

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[36.7]
	Not Done:	
	LNMT	Low [38.2] High [49.2] Unit %

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.34]
	Not Done:	
	LNMT	Low [4.40] High [5.50] Unit 10 ⁶ /cu mm
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[165]
	Not Done:	
	LNMT	Low [137] High [352] Unit 10 ³ /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[4.45]
	Not Done:	
	LNMT	Low [4.10] High [12.20] Unit 10 ⁶ /cu mm

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5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[2.39]
	Not Done:	
	LNMT	Low [1.50] High [7.90] Unit 10 ³ /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.00]
	Not Done:	
	LNMT	Low [0.00] High [0.50] Unit 10 ³ /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.45]
	Not Done:	
	LNMT	Low [0.30] High [1.10] Unit 10 ³ /uL

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5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.01]
	Not Done:	
	LNMT	Low [0.00] High [0.30] Unit 10 ³ /uL
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[1.58]
	Not Done:	
	LNMT	Low [1.10] High [3.40] Unit 10 ³ /uL

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Huntsville Hospital 101 Sivley Huntsville AL 35801]
3.	Collection Date:	Oct/19/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[13.1]
	Not Done:	
	LNMT	Low [12.2] High [16.7] Unit g/dL

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[37.0]
	Not Done:	
	LNMT	Low [38.2] High [49.2] Unit %

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.31]
	Not Done:	
	LNMT	Low [4.40] High [5.50] Unit 10 ⁶ /cu mm
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[160]
	Not Done:	
	LNMT	Low [137] High [352] Unit 10 ³ /uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[4.63]
	Not Done:	
	LNMT	Low [4.10] High [12.20] Unit 10 ³ /uL

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5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[12.5]
	Not Done:	
	LNMT	Low [1.50] High [7.90] Unit 10 ³ /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.00]
	Not Done:	
	LNMT	Low [0.00] High [0.50] Unit 10 ³ /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.48]
	Not Done:	
	LNMT	Low [0.30] High [1.10] Unit 10 ³ /uL

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5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.00]
	Not Done:	
	LNMT	Low [0.00] High [0.30] Unit 10 ³ /uL
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[2.94]
	Not Done:	
	LNMT	Low [1.50] High [7.90] Unit 10 ³ /uL

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Laboratory Data Hematology

1.	Lab Panel:	HEMATOLOGY
2.	Laboratory Name and Address	[Huntsville Hospital 101 Sivley Huntsville AL 35801]
3.	Collection Date:	Oct/20/2020
4.	Specimen Type:	BLOOD

Lab Result

5.a	Sponsor ID:	[1]
	Test:	Hemoglobin_PX1
	Result:	[13.1]
	Not Done:	
	LNMT	Low [12.2] High [16.7] Unit g/dL

5.b	Sponsor ID:	[2]
	Test:	Hematocrit_PX2
	Result:	[37.1]
	Not Done:	
	LNMT	Low [38.2] High [49.2] Unit 10^6/cu mm

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5.c	Sponsor ID:	[3]
	Test:	Erythrocytes_PX3
	Result:	[4.36]
	Not Done:	
	LNMT	Low [4.40] High [5.50] Unit 10^6/cu mm
5.d	Sponsor ID:	[5]
	Test:	Platelets_PX5
	Result:	[172]
	Not Done:	
	LNMT	Low [137] High [352] Unit 10^3/uL
5.e	Sponsor ID:	[7]
	Test:	Leukocytes_PX7
	Result:	[5.80]
	Not Done:	
	LNMT	Low [4.10] High [12.20] Unit 10^3/uL

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/14/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.f	Sponsor ID:	[608]
	Test:	Neutrophils_PX608
	Result:	[3.35]
	Not Done:	
	LNMT	Low [1.50] High [7.90] Unit 10 ³ /uL
5.g	Sponsor ID:	[609]
	Test:	Eosinophils_PX609
	Result:	[0.00]
	Not Done:	
	LNMT	Low [0.00] High [0.50] Unit 10 ³ /uL
5.h	Sponsor ID:	[612]
	Test:	Monocytes_PX612
	Result:	[0.44]
	Not Done:	
	LNMT	Low [0.30] High [1.10] Unit 10 ³ /uL

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** LOCAL LABORATORY DATA - REPEATING Hematology
Oct/14/2020

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.i	Sponsor ID:	[610]
	Test:	Basophils_PX610
	Result:	[0.02]
	Not Done:	
	LNMT	Low [0.00] High [0.50] Unit 10 ³ /uL
5.j	Sponsor ID:	[611]
	Test:	Lymphocytes_PX611
	Result:	[1.86]
	Not Done:	
	LNMT	Low [1.10] High [3.40] Unit 10 ³ /uL

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - COVID

Form Version: 15-Sep-2020 21:52

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details			Form Instance
1.	Oct/18/2020	Record Identifier:	Systolic:	Diastolic:	Repeating Pages
		1	130	72	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID
Oct/14/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

2.a	Record Identifier:	1	
	Systolic:	[130]	Comments
	Diastolic:	[72]	Comments
	Respiratory Rate in respirations/minute:	Not Done _____	Comments
		[]	
	Heart Rate in beats/minute:	[47]	Comments

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 15-Sep-2020 21:54

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
1.	Oct/16/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	80.0	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: VITAL SIGNS - PULSE OX ROOM AIR

Form Version: 10-Oct-2020 16:04

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Date:	Vital Signs Details		Form Instance
2.	Oct/19/2020	Record Identifier:	Oxygen Saturation	Repeating Pages
		1	95.0	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Oct/14/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

1.	Date:	Oct/16/2020
----	-------	-------------

Vital Signs Details

2.a	Record Identifier:	1
	SPO2 Pulse Oximetry %	[80.0]

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR
Oct/14/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: OXYGENATION PARAMETERS

Form Version: 06-Jul-2020 21:52

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Date Time of Assessment	Arterial Blood Gases PaO2	FiO2 (Fraction of Inhaled Oxygen)	Form Instance
1.				Repeating Pages

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** OXYGENATION PARAMETERS

Oct/14/2020

Form Version: 06-Jul-2020 21:52

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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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 1

Form: CONCOMITANT MEDICATIONS - VASOPRESSORS

Form Version: 06-Jul-2020 21:55

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** CONCOMITANT MEDICATIONS - VASOPRESSORS
Oct/14/2020

Form Version: 06-Jul-2020 21:55

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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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?	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1

Form: IMAGING

Form Version: 06-Jul-2020 21:53

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Date of Assessment	Location of Assessment	Imaging Method	Overall Assessment	Form Instance
1.	Oct/16/2020	CHEST	CT SCAN	ABNORMAL <i>If abnormal, specify findings:</i> Lungs: Multifocal ground glass opacities scattered throughout the lungs bilaterally. No Pleura effusions. Extensive coronary atherosclerotic classifications. Normal thickness of the Pericardium.	Repeating Pages

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING
Oct/14/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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Imaging

1.	Date of Assessment:	Oct/16/2020
2.	Location of Assessment:	CHEST
3.	Type of Imaging Exam:	CT SCAN
4.	Assessment:	ABNORMAL If abnormal, specify findings: [Lungs: Multifocal ground glass opacities scattered throughout the lungs bilaterally. No Pleura effusions. Extensive coronary atherosclerotic classifications. Normal thickness of the Pericardium.]

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/13/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date of Visit

1.	Date of Visit	Nov/13/2020
2.	Erroneous Visit	

COVID-19 Illness Visit

3.	COVID-19 Illness Visit:	COVID_A1
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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/13/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Nov/13/2020
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	[BPSXXR]
5.b	Sample ID	[BPSXXS]
5.c	Sample ID	[BPSXXT]
5.d	Sample ID	[BSHP4R]

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: DATE OF VISIT - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

COVID-19 Repeat Swab

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

Header Text: c4591001

Visit: POT_COVID_REPEAT_SWAB - New
Unscheduled Visit

Form: ELECTRONIC SAMPLE TRACKING - REPEAT SWAB

Form Version: 10-Oct-2020 15:57

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.	Sample ID	[]
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Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned - New Unscheduled Visit

Form: UNPLANNED VISIT

Form Version: 22-Apr-2020 21:04

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Unplanned Assessments

1.	Assessments	
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Header Text: c4591001

Visit: Logs

Form: ADVERSE EVENT REPORT

Form Version: 22-Apr-2020 21:02

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

#	Category	AE Identifier	Adverse Event	Start Date	Is the Adverse Event Still On going	Form Instance
1.	ADVERSE EVENT	1	acute coronary syndrome	Sep/25/2020 10:43	NO End Date Time: Sep/27/2020 UNK:UNK	Repeating Pages
2.	ADVERSE EVENT	2	left bundle branch block	Sep/25/2020 10:43	NO End Date Time: Sep/27/2020 UNK:UNK	Repeating Pages

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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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)	[acute coronary syndrome]
4.	Start Date Time:	Sep/25/2020 10:43
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/27/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	YES Is this serious event associated with congenital anomaly or birth defect? NO Did this serious event result in death? NO Did this serious event require or prolong hospitalization? YES Did this serious event result in persistent or significant disability/incapacity? NO Is this serious event life threatening? NO Other medically important serious event NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [history of diabetes type 2 and atrial fibrillation]

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
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
14.	Did the adverse event cause the subject to be discontinued from the study?	NO
15.	Serious Adverse Event Number: For Pfizer Use Only	[2020455722]

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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[Form Audit Trail](#)

Adverse Event Report

1.	Category:	ADVERSE EVENT
2.	AE ID:	[2]
3.	Adverse Event: (If possible specify diagnosis, not individual symptoms)	[left bundle branch block]
4.	Start Date Time:	Sep/25/2020 10:43
5.	Is the adverse event still ongoing?	NO End Date Time: Sep/27/2020 UNK:UNK
6.	Toxicity Grade:	2
7.	Is the adverse event serious? If Yes, NOTIFY PFIZER IMMEDIATELY. Fatal; Life-threatening; Inpatient hospitalization or prolongation of existing hospitalization; Persistent or significant disability/incapacity; Congenital anomaly/birth defect; Important medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).	NO
8.	Is this adverse event the result of a study Medication Error? If Yes, record the type of medication error on the Medication Error Log.	NO
9.	Is this event related to study treatment:	NOT RELATED If Not Related to study treatment(s), this event is due to: OTHER If Other, specify: [history of diabetes type 2 and atrial fibrillation]
10.	Latest Action Taken with Study Treatment:	NOT APPLICABLE
11.	Was a Concomitant Medication given?	YES

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Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT

Form Status: Data Complete, Frozen

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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

Header Text: c4591001

Visit: Logs

Form: MEDICATION ERROR

Form Version: 17-Jul-2020 21:54

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 17-Jul-2020 21:54

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: MEDICATION ERROR

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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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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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form: CONCOMITANT MEDICATIONS - NON STUDY
VACCINATIONS

Form Version: 22-Apr-2020 21:03

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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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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Header Text: c4591001

Visit: Logs

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Version: 22-Apr-2020 21:03

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: CONCOMITANT MEDICATIONS - PROHIBITED

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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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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Header Text: c4591001

Visit: Logs

Form: RADIATION TREATMENT

Form Version: 22-Apr-2020 21:02

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: RADIATION TREATMENT

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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Radiation Treatment

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

Header Text: c4591001

Visit: Logs

Form: TRANSFUSIONS

Form Version: 22-Apr-2020 21:03

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: TRANSFUSIONS

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Back to Form](#)

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

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form Version: 15-Sep-2020 21:55

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DISPOSITION - TREATMENT

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Treatment

1.	Date of Completion/Discontinuation /Death :	Oct/12/2020
2.	Phase of Disposition:	VACCINATION
3.	Status:	NO LONGER MEETS ELIGIBILITY CRITERIA
4.	Specify Status:	[The subject was diagnosed and had symptomatic Covid]

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VITAL SIGNS - TEMP

Form Version: 20-Feb-2021 02:16

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Vital Signs

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

Vital Signs Details

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

Header Text: c4591001

Visit: Unplanned Vaccination - Unscheduled

Form: VACCINATION

Form Version: 10-Dec-2020 02:26

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Vaccination

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

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Contact Outcome

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

Header Text: c4591001

Visit: Follow-Up - Unscheduled

Form Version: 15-Sep-2020 21:53

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DISPOSITION - FOLLOW-UP

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Disposition - Follow-Up

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

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/3/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: FURTHER VACCINATION CONFIRMATION

Form Version: 10-Dec-2020 02:25

Form Status: Data Complete, Frozen

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[eCRF Audit Trail History](#)

Further Vaccination Confirmation

1.	Select appropriate response - Is participant willing to return for Vaccination 3?	Participant is willing to return for Vaccination 3 Participant is: eligible per local/national recommendations and confirmed to have received only placebo at Vaccination 1/2
----	---	---

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: TREATMENT UNBLINDED

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Treatment Unblinded

1.	Date Treatment Unblinded :	Feb/3/2021
2.	Primary Reason for Unblinding:	ASSESS ELIGIBILITY FOR ADDITIONAL VACCINATION

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: WITHDRAWAL OF CONSENT

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Withdrawal Of Consent

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

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DEATH DETAILS CODED

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Death Details

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

Cause of Death

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

1.	Date of Visit	Feb/10/2021
2.	Erroneous Visit	

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: INFORMED CONSENT - FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Informed Consent - Further Vaccination

1.	Consent Was:	OBTAINED Date Written Consent Obtained Feb/10/2021
----	--------------	--

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[Form Comments](#)

Inclusion Criteria Not Met

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

Exclusion Criteria Met

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

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:31

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Disposition - Screening for Further Vaccination

1.	Date of Completion/Discontinuation /Death :	Feb/10/2021
2.	Phase of Disposition:	REPEAT SCREENING 1
3.	Status:	COMPLETED
4.	Specify Status:	[]

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	SERUM
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
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	[BPSYMN]
5.b	Sample ID	[BPSYMP]
5.c	Sample ID	[BPSYMR]
5.d	Sample ID	[BLB6SH]

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

1.	Data Origin	SITE
2.	Sample Type	NASAL_SWAB
3.	Sample Collected?	YES Date of Collection: Feb/10/2021
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	[BRJ2J6]
-----	-----------	----------

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Feb/10/2021 15:29
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Date of Visit

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

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Electronic Sample Tracking

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

Aliquot

Please enter barcode for each aliquot.

5.a	Sample ID	[BRJ2MV]
-----	-----------	----------

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Vaccination

1.	Was there a temporary delay of vaccination?	NO
2.	Treatment Name	[BNT162b2]
3.	Formulation:	INJECTION
4.	Dose Date Time:	Mar/1/2021 14:03
5.	Anatomical Location:	DELTOID MUSCLE
6.	Body Side:	LEFT
7.	Route:	INTRAMUSCULAR
8.	Actual Dose:	[30.0]
9.	Unit:	ug
10.	Timeframe Subject Was Observed	30 MINUTES
11.	Was the subject observed for at least the protocol specified observation period after investigational product administration?	YES

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V103_MONTH1

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V104_MONTH6

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Date of Visit

1.	Date of Visit	//
2.	Erroneous Visit	

Header Text: c4591001

Visit: V105_MONTH18

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: CONTACT OUTCOME

Form Status: Not Started

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Contact Outcome

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

Header Text: c4591001

Visit: FURTHER_VACCINATION_EOT -
Unscheduled

Form: DISPOSITION - TREATMENT

Form Version: 20-Feb-2021 02:26

Form Status: Not Started

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Disposition - Treatment

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

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: SUBJECT STATUS

Form Status: Data Complete, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Subject Status

1.	Subject Status	DISCONTINUED
2.	Subject Status Date	Oct/12/2020

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM

Form Status: Data Complete, Signed, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[eCRF Audit Trail History](#)

Casebook Signature Form

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

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

[Audit Trail](#)

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6) (b) (6)	Approved	Mar-12-2021 13:19:55 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:53

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: INCLUSION/EXCLUSION CRITERIA - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Sep-21-2020 13:53:56 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
Form	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
1	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
2	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
3	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
4	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

[Back to Form](#)

Item	Date	User	Comment
5	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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Item	Date	User	Comment
6	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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Item	Date	User	Comment
7	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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Item	Date	User	Comment
8	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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Item	Date	User	Comment
9	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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Item	Date	User	Comment
10	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - Comments

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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Item	Date	User	Comment
11	Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	subject did not receive injection due to testing positive for covid 19 in between visit 1 (vax 1) and visit 2 (vax 2). <hr/> Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form <hr/> Not Applicable
Form	Nov-05-2020 15:07:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
1	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
3	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
4	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
6	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

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Item	Date	User	Comment
7	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
8	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Comments
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
9	Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Per Medical monitor the test this subject had should not be reported on this form
			Not Applicable

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-20-2020 15:21:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	normal <42 Enzu?L

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-20-2020 15:21:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	normal <42 Enzu?L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-20-2020 15:21:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	normal <42 Enzu?L

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

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Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-20-2020 15:21:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	normal <42 Enzu?L

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Oct-20-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	normal <39 EnzU/L

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.c	Oct-20-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	normal <39 EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Generated By: (b) (4)

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Item	Date	User	Comment
5.c	Oct-20-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	normal <39 EnzU/L

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site Name: (1047) Medical Affiliated Research Center

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

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Item	Date	User	Comment
5.c	Oct-20-2020 15:22:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	normal <39 EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.d	Oct-20-2020 15:24:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Normal 39-117 EnzU/L

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.d	Oct-20-2020 15:24:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Normal 39-117 EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.d	Oct-20-2020 15:24:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Normal 39-117 EnzU/L

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.d	Oct-20-2020 15:24:03 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	Normal 39-117 EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-22-2020 12:39:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L
5.b	Oct-21-2020 14:12:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	unit of measure is EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.b	Oct-22-2020 12:39:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L
5.b	Oct-21-2020 14:12:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	unit of measure is EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

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Item	Date	User	Comment
5.b	Oct-22-2020 12:39:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L
5.b	Oct-21-2020 14:12:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	unit of measure is EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Item	Date	User	Comment
5.b	Oct-22-2020 12:39:30 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L
5.b	Oct-21-2020 14:12:20 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	unit of measure is EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

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

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Item	Date	User	Comment
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

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Item	Date	User	Comment
5.c	Oct-22-2020 12:40:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Subject No: 10471252

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

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Item	Date	User	Comment
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

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Subject Initials: ---

Generated By: (b) (4)

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5.c	Oct-22-2020 12:40:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

Form Version: 10-Oct-2020 15:58

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Site No: 1047

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5.d	Oct-22-2020 12:41:25 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Comments

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

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Header Text: c4591001

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Header Text: c4591001

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5.d	Oct-22-2020 12:44:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L

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5.d	Oct-22-2020 12:44:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L

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5.d	Oct-22-2020 12:44:02 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	EnzU/L

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5.d	Oct-21-2020 16:15:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	X10^3/mcL

Header Text: c4591001

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Item	Date	User	Comment
5.d	Oct-21-2020 16:15:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	X10^3/mcL

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5.d	Oct-21-2020 16:15:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	X10^3/mcL

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5.d	Oct-21-2020 16:15:24 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	X10^3/mcL
5.d	Oct-21-2020 16:14:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	x10 3/mcL

Header Text: c4591001

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5.e	Oct-23-2020 07:42:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl

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Item	Date	User	Comment
5.e	Oct-23-2020 07:42:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl
5.e	Oct-21-2020 16:18:31 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	X10^3/mcL

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5.e	Oct-23-2020 07:42:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl

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5.e	Oct-23-2020 07:42:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl
5.e	Oct-21-2020 16:19:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	10^3/mcL

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5.f	Oct-23-2020 07:42:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10 ³ /mcl
5.f	Oct-22-2020 12:15:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	units not available in drop down x10 ³ /mcl

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5.f	Oct-23-2020 07:42:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10 ³ /mcl
5.f	Oct-22-2020 12:15:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	units not available in drop down x10 ³ /mcl
5.f	Oct-21-2020 16:17:47 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	%

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5.f	Oct-22-2020 12:15:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	units not available in drop down x10 ³ /mcl

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5.f	Oct-23-2020 07:42:38 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10 ³ /mcl
5.f	Oct-22-2020 12:15:58 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	units not available in drop down x10 ³ /mcl

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5.g	Oct-23-2020 07:42:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl
5.g	Oct-21-2020 16:21:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	high and low not provided. % only

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5.g	Oct-21-2020 16:21:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	high and low not provided. % only
5.g	Oct-21-2020 16:20:12 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	%

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5.g	Oct-21-2020 16:21:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	high and low not provided. % only

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5.g	Oct-23-2020 07:42:57 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl
5.g	Oct-22-2020 12:19:55 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	x10^3/mcl not available in drop down
5.g	Oct-21-2020 16:21:34 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	high and low not provided. % only

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5.h	Oct-21-2020 16:26:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.
5.h	Oct-21-2020 16:25:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.h	Oct-21-2020 16:26:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.
5.h	Oct-21-2020 16:25:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.
5.h	Oct-21-2020 16:25:35 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.h	Oct-21-2020 16:26:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.
5.h	Oct-21-2020 16:25:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.h	Oct-22-2020 12:24:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl
5.h	Oct-21-2020 16:26:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.
5.h	Oct-21-2020 16:25:49 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.i	Oct-23-2020 07:41:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl
5.i	Oct-21-2020 16:26:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.i	Oct-23-2020 07:41:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl
5.i	Oct-21-2020 16:26:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.
5.i	Oct-21-2020 16:23:33 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.i	Oct-23-2020 07:41:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10^3/mcl
5.i	Oct-21-2020 16:26:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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Item	Date	User	Comment
5.i	Oct-23-2020 07:41:54 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	X10 ³ /mcl
5.i	Oct-22-2020 12:29:22 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	x10 ³ /mcl
5.i	Oct-21-2020 16:26:53 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Oct-21-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Oct-21-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.
5.j	Oct-21-2020 16:24:39 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Oct-21-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Comments

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
5.j	Oct-22-2020 12:33:10 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	x10 ³ /mcl
5.j	Oct-21-2020 16:27:05 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	No normal lab range provided on lab results. % only.

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments
Oct/14/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.a	Oct-20-2020 16:37:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respiration not recorded
2.a	Oct-19-2020 14:53:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respirations not done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments
Oct/14/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.a	Oct-20-2020 16:37:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respiration not recorded
2.a	Oct-19-2020 14:53:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respirations not done

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments
Oct/14/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.a	Oct-21-2020 09:09:44 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respiration not recorded Not Done
2.a	Oct-20-2020 16:37:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respiration not recorded
2.a	Oct-19-2020 14:53:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respirations not done

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Comments
Oct/14/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
2.a	Oct-20-2020 16:37:06 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respiration not recorded
2.a	Oct-19-2020 14:53:07 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6)	respirations not done

Header Text: c4591001

Visit: V101_VAX3

Form: INCLUSION/EXCLUSION CRITERIA - FURTHER
VACCINATION - Comments

Form Version: 10-Dec-2020 02:30

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Item	Date	User	Comment
Form	Feb-11-2021 14:20:08 (UTC-06:00) Central Time (US & Canada)	(b) (4), (b) (6) (b) (4), (b) (6)	Not Applicable

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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

- CRF_Sign

Name	Signature Meaning	Date	Type	Action
(b) (6) (b) (6)	Approved	Mar-12-2021 13:19:55 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed

Affidavit:

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Feb-04-2021 10:25:01 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6) (b) (6)	Approved	Jan-21-2021 09:07:43 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6) 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-11-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6) (b) (6)	Approved	Dec-02-2020 13:02:48 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form: CASEBOOK SIGNATURE FORM - Signature History

Form Version: 22-Apr-2020 21:04

Form Status: Data Complete, Signed, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Affidavit:

By my dated signature below, I, (b) (6) 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-02-2020 08:11:26 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6) (b) (6)	Approved	Nov-27-2020 18:37:11 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6) verify that all case report form pages accurately display the results of the examinations, tests, evaluations and treatments performed on this subject.

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

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

(b) (6)	N/A	Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)		Edit - All signatures invalidated
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Affidavit:

N/A

(b) (6) (b) (6)	Approved	Nov-16-2020 15:31:36 (UTC-06:00) Central Time (US & Canada)	BOOK	Signed
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Affidavit:

By my dated signature below, I, (b) (6) 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.

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 15-Sep-2020 21:55

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: COHORT SELECTION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Select appropriate response - Protocol version

Date	Location	User	Value	Reason
Sep-21-2020 13:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 08 SEP 2020	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 13:53:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: STAGE 3 COHORTS	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: MAIN INFORMED CONSENT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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I. Consent Was:

Date	Location	User	Value	Reason
Sep-21-2020 13:53:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: COHORT_SELECTION

Form: DEMOGRAPHY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Subject ID

Date	Location	User	Value	Reason
Sep-21-2020 13:53:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10471252	Item copied from previous form

2. Birth Date:

Date	Location	User	Value	Reason
Sep-21-2020 13:53:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: (b) (6) 1957	Enrollment Entry

3. Sex:

Date	Location	User	Value	Reason
Sep-21-2020 13:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: MALE	Initial Entry

4. Ethnicity:

Date	Location	User	Value	Reason
Sep-21-2020 13:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT HISPANIC OR LATINO(A) OR OF SPANISH ORIGIN	Initial Entry

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

Date	Location	User	Value	Reason
Sep-21-2020 13:53:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: WHITE	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Sep-21-2020 13:53:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:52

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DISPOSITION - SCREENING - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Date of Completion/Discontinuation/Death

Date	Location	User	Value	Reason
Sep-21-2020 13:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Sep-21-2020 13:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENING	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Sep-21-2020 13:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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I.a

Date	Location	User	Value	Reason
Sep-22-2020 10:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 1 Medical History Term: diabetes type I Start Date: UNK/UNK/2010 Ongoing: YES	Initial Entry

I.a Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: diabetes type II	Initial Entry

I.a Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.a Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.b

Date	Location	User	Value	Reason
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Sep-22-2020 10:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 2 Medical History Term: atrial fibrillation Start Date: UNK/UNK/2012 Ongoing: YES	Initial Entry
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I.b Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: atrial fibrillation	Initial Entry

I.b Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2012	Initial Entry

I.b Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.c

Date	Location	User	Value	Reason
Sep-22-2020 10:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 3 : Medical History Term: gallstones	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

			Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010
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I.c Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: gallstones	Initial Entry

I.c Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.c Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:18:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.d

Date	Location	User	Value	Reason
Sep-22-2020 10:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 4	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

			Medical History Term: torn rotator cuff (right) Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	
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I.d Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 4	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: torn rotator cuff (right)	Initial Entry

I.d Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.d Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:19:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.e

Date	Location	User	Value	Reason
Sep-22-2020 10:19:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 5	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

			Medical History Term: bilateral broken ankles Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	
--	--	--	--	--

I.e Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:19:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:19:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral broken ankles	Initial Entry

I.e Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:19:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.e Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:19:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.f

Date	Location	User	Value	Reason
Sep-22-2020 10:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Line/MH Number: 6	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

			Medical History Term: ace inhibitor allergy Start Date: UNK/UNK/2015 Ongoing: YES	
Sep-22-2020 10:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 6 Medical History Term: ace inhibitor allergy Start Date: UNK/UNK/2015 Ongoing:	Initial Entry

If Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 6	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ace inhibitor allergy	Initial Entry

If Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:19:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

If Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

I.g

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-22-2020 10:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 7 : Medical History Term: cholecystectomy Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	Initial Entry

I.g Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: cholecystectomy	Initial Entry

I.g Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.g Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:21:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.h

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-22-2020 10:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 8 Medical History Term: rotator cuff repair (right) Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2010	Initial Entry

I.h Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 8	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: rotator cuff repair (right)	Initial Entry

I.h Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

I.h Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:22:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

I.i

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-22-2020 10:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number: 9 Medical History Term: left knee replacement Start Date: UNK/UNK/2015 Ongoing: NO End Date: UNK/UNK/2015	Initial Entry

L.i Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 9	Initial Entry

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

Date	Location	User	Value	Reason
Sep-22-2020 10:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: left knee replacement	Initial Entry

L.i Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2015	Initial Entry

L.i Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:22:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2015	Initial Entry

L.j

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Date	Location	User	Value	Reason
Sep-22-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Line/MH Number 10 : Medical History T bilateral fused an erm: kles Start Date: UNK/UNK/2010 Ongoing: NO End Date: UNK/UNK/2 010	Initial Entry

I,j Line/MH Number:

Date	Location	User	Value	Reason
Sep-22-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 10	Initial Entry

I,j Disease/Syndrome/Surgery/Non-Drug Allergies/Drug Allergies:

Date	Location	User	Value	Reason
Sep-22-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: bilateral fused ankles	Initial Entry

I,j Start Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: UNK/UNK/2010	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: GENERAL MEDICAL HISTORY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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I,j Ongoing:

Date	Location	User	Value	Reason
Sep-22-2020 10:23:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date: UNK/UNK/2010	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:57

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: HIV STATUS - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Select appropriate response - What is the subject HIV status?

Date	Location	User	Value	Reason
Sep-22-2020 10:17:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject is NOT known to be HIV POSITIVE	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Weight:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 245.0	Initial Entry

3. Unit:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LB	Initial Entry

4. Height:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 73.0	Initial Entry

5. Unit:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: in	Initial Entry

6. Body Mass Index:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 32.3	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 15-Sep-2020 21:56

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VITAL SIGNS - BASELINE - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

7.a

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location:: FOREHEAD	Initial Entry

7.a Record Identifier:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

7.a Temperature:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.5	Initial Entry

7.a Unit:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

7.a Temperature Location:

Date	Location	User	Value	Reason
Sep-22-2020 10:17:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: RANDOMIZATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Randomization Date :

Date	Location	User	Value	Reason
Sep-21-2020 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020	Initial Entry

2. Randomization Number:

Date	Location	User	Value	Reason
Sep-21-2020 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 262745	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 13:56:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 13:56:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 13:56:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 13:56:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 13:56:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 13:56:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BM950F	Initial Entry

5.a Sample ID

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-22-2020 13:56:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BM950F	Initial Entry

5.b

Date	Location	User	Value	Reason
Sep-22-2020 13:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BM950G	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 13:57:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BM950G	Initial Entry

5.c

Date	Location	User	Value	Reason
Sep-22-2020 13:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BM950H	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 13:57:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BM950H	Initial Entry

5.d

Date	Location	User	Value	Reason
Sep-22-2020 13:57:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BK8YTL	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 13:57:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BK8YTL	Initial Entry

5.e

Date	Location	User	Value	Reason
Sep-22-2020 13:57:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BK8YTM	Initial Entry

5.e Sample ID

Date	Location	User	Value	Reason
Sep-22-2020 13:57:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BK8YTM	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Sep-22-2020 13:56:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Sep-22-2020 13:56:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Sep-22-2020 13:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Sep-22-2020 13:56:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Sep-22-2020 13:56:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: YES Date of Collection: Sep/21/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Sep-22-2020 13:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: BM94ZF	Initial Entry

5.a Sample ID

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Sep-22-2020 13:56:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: BM94ZF	Initial Entry

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Sep-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Sep-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLINDED THERAPY	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Sep-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Sep-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/21/2020 14:10	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Sep-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Sep-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

7. Route:

Date	Location	User	Value	Reason
Sep-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Sep-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: THE PROTOCOL SPECIFIED OBS ERVATION 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-22-2020 10:16:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V1_DAY1_VAX1_L

Form Version: 06-Jul-2020 21:53

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: REACTOGENICITY DIARY - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Select appropriate response - Reactogenicity diary collection

Date	Location	User	Value	Reason
Sep-21-2020 13:54:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO - REACTOGENICITY E-DIARY NOT COLLECTED FOR THIS SUBJECT	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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I. Date of Visit

Date	Location	User	Value	Reason
Nov-15-2020 12:01:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Steven Finegan Prod (b) (4)	Query 1: Closed	Response satisfies query
Nov-15-2020 10:56:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Patient out of window due to Covid Illness.
Nov-14-2020 00:15:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	PDQ: DOV at this visit is out of window (30 day) from DOV (21/Sep /2020) at V1D1VX1L. Please either update DOV or confirm whether visit is out of window due to temporary delay of vaccination/ else provide details as appropriate.
Nov-13-2020 13:59:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/13/2020	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Date:

Date	Location	User	Value	Reason
Nov-13-2020 14:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Nov/13/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Nov-13-2020 14:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Temperature: 97.5 Temperature Unit: F Temperature Location: FOREHEAD	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Nov-13-2020 14:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Temperature:

Date	Location	User	Value	Reason
Nov-13-2020 14:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 97.5	Initial Entry

2.a Unit:

Date	Location	User	Value	Reason
Nov-13-2020 14:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: F	Initial Entry

2.a Temperature Location:

Date	Location	User	Value	Reason
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 10-Oct-2020 16:01

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VITAL SIGNS - TEMP - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

Nov-13-2020 14:48:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FOREHEAD	Initial Entry
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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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Nov-13-2020 13:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-13-2020 13:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-13-2020 13:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-13-2020 13:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-13-2020 13:59:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-13-2020 13:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSXTZ	Initial Entry

5.a Sample ID

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Nov-13-2020 13:59:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BPSXTZ	Initial Entry

Header Text: c4591001

Visit: V2_VAX2_L

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Locked, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

7. Route:

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

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

Date	Location	User	Value	Reason
Nov-13-2020 14:50:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V3_MONTH1_POSTVAX2_L

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Dec-11-2020 11:38:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Dec/11/2020	Initial Entry

Header Text: c4591001**Visit:** V3_MONTH1_POSTVAX2_L**Form:** ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY - eCRF Audit Trail History**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Data Origin**

Date	Location	User	Value	Reason
Dec-11-2020 11:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Dec-11-2020 11:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Dec-11-2020 11:39:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Dec-11-2020 11:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Dec-11-2020 11:39:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Dec/11/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Dec-11-2020 11:39:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BJYB47	Initial Entry

5.a Sample ID

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, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Dec-11-2020 11:39:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BJYB47	Initial Entry

5.b

Date	Location	User	Value	Reason
Dec-11-2020 11:39:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSY40	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Dec-11-2020 11:39:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSY40	Initial Entry

5.c

Date	Location	User	Value	Reason
Dec-11-2020 11:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSY3Z	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Dec-11-2020 11:39:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSY3Z	Initial Entry

5.d

Date	Location	User	Value	Reason
Dec-11-2020 11:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSY3Y	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Dec-11-2020 11:39:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSY3Y	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** DATE OF VISIT - ILLNESS ONSET - eCRF Audit Trail History
Oct/14/2020**Form Version:** 22-Apr-2020 21:03**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Oct-15-2020 09:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Deleted	Close Auto Query
Oct-15-2020 09:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	Date of Visit is completed but Date of Assessment in the Signs and Symptoms form is missing. Please review and update as appropriate.
Oct-15-2020 09:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	Date of Visit is completed but Date of Collection in both Nasal Swab Self and Nasal Swab are missing. Please review and update as appropriate.
Oct-15-2020 09:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Oct-15-2020 09:47:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: COVID_A	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Date of First Symptom Started:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	Initial Entry

3. Symptoms Ongoing?

Date	Location	User	Value	Reason
Feb-18-2021 14:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Feb-18-2021 08:53:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	New Information
Feb-18-2021 08:53:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO Date of Last Symptom Resolved: Nov/15/2020	New Information
Feb-15-2021 05:44:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM Query: Please confirm the symptoms are still ongoing for this COVID Illness. If all symptoms for this illness are resolved; please update the Last Symptoms Resolved Date else

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

				clarify.
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.a

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: FEVER Symptom Present: YES	Initial Entry

4.a Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: FEVER	Initial Entry

4.a Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.b

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW OR INCREASED COUGH Symptom Present: YES	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

4.b Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED COUGH	Initial Entry

4.b Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.c

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptom: NEW OR INCREASED SHORTNESS OF BREATH Symptom Present: YES	Initial Entry

4.c Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SHORTNESS OF BREATH	Initial Entry

4.c Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.d

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF
Oct/14/2020 Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: CHILLS Symptom Present: NO	Initial Entry

4.d Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHILLS	Initial Entry

4.d Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.e

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASE : D MUSCLE PAIN Symptom Present: YES	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

4.e Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED MUSCLE PAIN	Initial Entry

4.e Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

4.f

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: NEW LOSS OF TASTE OR SMELL Symptom Present: NO	Initial Entry

4.f Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW LOSS OF TASTE OR SMELL	Initial Entry

4.f Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.g

Date	Location	User	Value	Reason
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms NEW OR INCREASE : D SORE THROAT Symptom NO Present:	Initial Entry
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4.g Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEW OR INCREASED SORE THR OAT	Initial Entry

4.g Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4.h

Date	Location	User	Value	Reason
Oct-19-2020 14:32:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: YES	New Information
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms: DIARRHEA Symptom Present: NO	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

4.h Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> DIARRHEA	Initial Entry

4.h Was symptom present?

Date	Location	User	Value	Reason
Oct-19-2020 14:32:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> YES	New Information
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

4.i

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Symptoms: VOMITING Symptom Present: NO	Initial Entry

4.i Symptoms:

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> VOMITING	Initial Entry

4.i Was symptom present?

Date	Location	User	Value	Reason
Oct-15-2020 09:48:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** SIGNS AND SYMPTOMS OF POTENTIAL COVID-19 - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Not Complete

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.a

Date	Location	User	Value	Reason
Oct-15-2020 09:49:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Symptoms - Other: Headache	Initial Entry

5.a Symptoms - Other Text:

Date	Location	User	Value	Reason
Oct-15-2020 09:49:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Headache	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - Audit Trail
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-15-2020 09:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Actual Date of Collection:

Date	Location	User	Value	Reason
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-05-2020 15:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	per medical monitor the test this subject recieved should not be reported on this form
Oct-15-2020 09:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Specimen Type:

Date	Location	User	Value	Reason
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-05-2020 15:03:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Per Medical monitor the test this subject had should not be reported on this form
Oct-15-2020 09:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SWABBED MATERIAL	Initial Entry

3. Specimen Collection Location:

Date	Location	User	Value	Reason
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Nov-05-2020 15:06:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	changed per query
Oct-15-2020 09:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NASOPHARYNX	Initial Entry

4. Assay Code and Description:

Date	Location	User	Value	Reason
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-05-2020 15:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	per medical monitor the test this subject recieved should not be reported on this form
Oct-15-2020 09:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SEVERE ACUTE RESP SYNDROM E CORONAVIRUS 2	Initial Entry

5. Device Type:

Date	Location	User	Value	Reason
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Not Applicable	Initial Entry
Nov-05-2020 15:03:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry:	per medical monitor the test this subject recieved should not be reported on this form
Oct-15-2020 09:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SARS-COV-2 DIAGNOSTIC TEST	Initial Entry

6. Trade Name:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Nov-05-2020 22:42:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-05-2020 15:04:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	change per query
Nov-05-2020 15:04:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	change per query
Nov-05-2020 07:10:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Medical monitor: This test is an Antigen Fluorescent Immunoassay (FIA) not a SARS-CoV-2 NAAT test. This test result should not be reported on this form
Nov-04-2020 09:38:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	This is not an antigen test this was a SARS PCR test. Would you like for me to remove it or leave it in place
Nov-03-2020 19:15:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: This test is an Antigen Fluorescent Immunoassay (FIA) not a SARS-CoV-2 NAAT test. This test result should not be reported on this form.
Oct-15-2020 10:07:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

7. Test Result:

Date	Location	User	Value	Reason
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry

Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Oct/14/2020**Form Version:** 06-Jul-2020 21:54**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-05-2020 15:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	changed per query
Oct-22-2020 14:52:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 12:00:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	confirm vaccination 2 will not be done.
Oct-21-2020 18:08:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Given that subject is symptomatic and has positive COVID local test result prior to vaccination 2, please confirm as to whether the subject meets exclusion criteria? If so, VAX#2 should NOT be done and EOT CRF should be completed per CCG
Oct-16-2020 15:18:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: POSITIVE	Transcription Error
Oct-15-2020 09:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NEGATIVE	Initial Entry

8. Comments/Findings/Details:

Date	Location	User	Value	Reason
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-05-2020 15:06:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	changed per query
Oct-15-2020 10:07:26 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sofia II Sars Atigen FIA	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** MICROBIOLOGY SPECIMEN - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4), (b) (6)	
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9. Trade Name Other, Specify:

Date	Location	User	Value	Reason
Nov-05-2020 15:09:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Applicable	Initial Entry
Nov-05-2020 15:08:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	changed per query
Oct-15-2020 10:07:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Quidel	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 09:54:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 09:54:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB_SELF	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-16-2020 07:58:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Oct-16-2020 05:56:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 09:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Oct-15-2020 09:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-15-2020 09:56:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Oct/14/2020	Transcription Error

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** ELECTRONIC SAMPLE TRACKING - NASAL SWAB SELF - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Oct-15-2020 09:54:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	'Sample Collected?' is marked as No and 'If no sample was collected or sample was not collected according to protocol, please provide reason' is missing. Please review and update as appropriate.
Oct-15-2020 09:54:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-16-2020 07:58:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sample ID: CV46611	Initial Entry

5.a Sample ID

Date	Location	User	Value	Reason
Oct-16-2020 07:58:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: CV46611	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Oct-15-2020 09:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Oct-15-2020 09:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Oct-15-2020 09:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

4. If no sample was collected or sample was not collected according to protocol, please provide reason:

Date	Location	User	Value	Reason
Oct-15-2020 09:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: no office visit	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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I.a

Date	Location	User	Value	Reason
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts: NO	Initial Entry
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: SPECIALIST Occurrence of Visits or Contacts:	Initial Entry

I.a Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: SPECIALIST	Initial Entry

I.a Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-18-2020 07:25:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated.
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Oct-16-2020 02:42:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Occurrence of Visits or Contacts" is missing. Kindly review and update.

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/14/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

I.b

Date	Location	User	Value	Reason
Oct-19-2020 14:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	New Information
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts: NO	Initial Entry
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: EMERGENCY ROOM Occurrence of Visits or Contacts:	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/14/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

I.b Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: EMERGENCY ROOM	Initial Entry

I.b Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-19-2020 14:32:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	New Information
Oct-18-2020 07:26:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated.
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Oct-16-2020 02:43:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Occurrence of Visits or Contacts" is missing. Kindly review and update.

I.c

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: PRIMARY CARE PHYSICIAN Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/14/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

I.c Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: PRIMARY CARE PHYSICIAN	Initial Entry

I.c Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

I.d

Date	Location	User	Value	Reason
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or r Contacts: NO	Initial Entry
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: URGENT CARE Occurrence of Visits or r Contacts:	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/14/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

1.d Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: URGENT CARE	Initial Entry

1.d Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-18-2020 07:26:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated.
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Oct-16-2020 02:43:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Occurrence of Visits or Contacts" is missing. Kindly review and update.

1.e

Date	Location	User	Value	Reason
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts: NO	Initial Entry
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: TELEPHONE CONSULTATION Occurrence of Visits or Contacts:	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/14/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

I.e Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: TELEPHONE CONSULTATION	Initial Entry

I.e Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-18-2020 07:26:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Data updated.
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Initial Entry
Oct-16-2020 08:01:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry
Oct-16-2020 02:43:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Occurrence of Visits or Contacts" is missing. Kindly review and update.

I.f

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Type of Practitioner: OTHER Occurrence of Visits or Contacts: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/14/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

1.f Physician or Healthcare Professional:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OTHER	Initial Entry

1.f Occurrence of Visits or Contacts:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Number of Visits or Contacts:</i> 1	Initial Entry

2. Other Type of Practitioner Specify:

Date	Location	User	Value	Reason
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Covid Test Center/Regional hospital	Initial Entry

3. Has the subject been hospitalized due to potential COVID-19 illness?

Date	Location	User	Value	Reason
Nov-10-2020 10:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-09-2020 09:07:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	will answer ad information becomes available
Nov-06-2020 17:50:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Subject had COVID-19 Illness and was hospitalized. Please enter on the relevant CRF form any available information (vital signs, pulse oxymet, respiratory treatment,

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HEALTH CARE UTILIZATION - eCRF Audit Trail History
Oct/14/2020

Form Version: 10-Oct-2020 15:59

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

				lab results, imaging...). Please make every effort to obtain this information.
Oct-19-2020 14:32:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Has the subject been in intensive care due to potential COVID-19 i llness? NO	New Information
Oct-15-2020 09:55:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** HOSPITALIZATION DETAILS - Audit Trail
Oct/14/2020

Form Version: 22-Apr-2020 21:02

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-19-2020 14:33:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: HOSPITALIZATION DETAILS - eCRF Audit Trail History
Oct/14/2020

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Hospitalization Category:

Date	Location	User	Value	Reason
Oct-19-2020 14:33:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HOSPITALIZATION STATUS	Initial Entry

2. Hospitalization Term:

Date	Location	User	Value	Reason
Oct-19-2020 14:33:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HOSPITAL	Initial Entry

3. Admission Date:

Date	Location	User	Value	Reason
Oct-19-2020 14:33:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

4. Ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 14:33:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - Audit Trail
Oct/14/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-19-2020 14:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: RESPIRATORY TREATMENT - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. What is the treatment Identifier?

Date	Location	User	Value	Reason
Oct-19-2020 14:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

2. Concomitant Non-drug Treatment Pre-specified:

Date	Location	User	Value	Reason
Oct-19-2020 14:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: YES	Initial Entry

3. Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 14:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: HIGH FLOW OXYGEN THERAPY	Initial Entry

4. Treatment:

Date	Location	User	Value	Reason
Oct-19-2020 14:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HIGH FLOW OXYGEN THERAPY	Initial Entry

5. Start Date:

Date	Location	User	Value	Reason
Oct-19-2020 14:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

6. Ongoing?

Date	Location	User	Value	Reason
Oct-19-2020 14:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** RESPIRATORY TREATMENT - eCRF Audit Trail History
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Form Version: 06-Jul-2020 21:53

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

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Generated By: (b) (4)

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(b) (4), (b) (6)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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1. Category of Clinical Event:

Date	Location	User	Value	Reason
Oct-15-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: POTENTIAL COVID-19 ILLNESS	Initial Entry

2. Was a diagnosis obtained for Potential COVID-19 Illness?

Date	Location	User	Value	Reason
Nov-16-2020 15:17:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Ruth Bailey (b) (4)	Query 3: Closed	Response satisfies query
Nov-15-2020 15:01:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	This subject tested positive for Covid was diagnosed with Covid and hospitalized and treated for Covid. The Medical monitor said that the test that was used for his initial positive test could not be listed on the local Covid test page in the crf
Nov-14-2020 15:55:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINQUERY: Please work with CRA to address this. Per CRF Completion Guidelines, section 8.33.3, ONLY enter/update diagnosis if locally performed test is positive and captured on COVID TEST CRF.
Nov-13-2020 16:17:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	there is no covid test for his hospitalization.

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on **Form:** ILLNESS DETAILS - eCRF Audit Trail History
Oct/14/2020**Form Version:** 06-Jul-2020 21:52**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Nov-13-2020 16:11:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINQUERYL Did subject get tested at the hospital? Please add any local SARS-CoV-2-NAAT test results to the COVID TEST CRF.
Nov-13-2020 14:12:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	subject was hospitalized and diagnosed and treated for Covid 19
Nov-13-2020 10:51:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	CLINQUERY: Per CCG 8.33.3, DO NOT enter or update diagnosis due to central lab testing results. Please update appropriately.
Nov-13-2020 08:50:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Subject was diagnosed with covid 19 the study swab was positive for Covid.
Nov-12-2020 16:44:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINQUERY: Please clarify diagnosis of COVID 19? The local COVID TEST page does not indicate a POSITIVE test. If no diagnosis made, update to NO. Please update accordingly.
Oct-25-2020 19:13:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-22-2020 08:11:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-21-2020 21:16:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: Patient has positive covid test and should not receive 2nd vaccine. Please complete EOT

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: ILLNESS DETAILS - eCRF Audit Trail History
Oct/14/2020

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Form Status: Data Complete, Frozen, Verified

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Generated By: (b) (4)

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				CRF confirming patient 'no longer meets eligibility criteria' with reason 'subject tested positive for COVID19'. patient should continue in FU part of the study
Oct-16-2020 15:48:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-16-2020 15:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	corrected
Oct-16-2020 13:14:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: COVID TEST CRF page notes the test result was Negative. Was a COVID-19 test positive for the diagnosis to be 'COVID-19'? Please clarify.
Oct-15-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES <i>Respiratory Illness Diagnosis:</i> Covid-19 Date of Diagnosis: Oct/14/2020	Initial Entry

3. Toxicity Grade:

Date	Location	User	Value	Reason
Oct-15-2020 09:57:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

Form Version: 15-Sep-2020 21:51

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-19-2020 14:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-07-2020 23:37:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Closed	data correct as reported
Dec-07-2020 23:34:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 4: Opened	DM: A carriage return is still identified, in order to avoid processing enter please enter lab address all in single line without hitting enter key or copy paste. Thank you.
Dec-02-2020 10:06:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Data updated.
Dec-02-2020 08:11:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Dec-02-2020 08:11:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Avenue Huntsville Alabama	Transcription Error
Dec-02-2020 05:07:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	DM RQ1 :A carriage return is still identified, Please click into the enterable page and press delete and backspace multiple times to remove the characters. Do not press enter key, just

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:51

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

				type lab name all in single line with comma separated.
Nov-11-2020 13:05:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-11-2020 07:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-11-2020 07:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Avenue Huntsville Alabama 35801	Transcription Error
Nov-11-2020 02:02:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Opened	DM: A carriage return is identified, please do not press enter, tab key or extra space or copy paste, just type lab name all in single line with comma separated. Thank you.
Oct-23-2020 02:48:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 12:03:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-22-2020 12:03:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Avenue Huntsville Alabama 35801	Transcription Error
Oct-22-2020 08:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: A trailing space is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).

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Header Text: c4591001

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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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Oct-19-2020 14:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital Systems 101 Sivley Avnue Huntsville, Alabama	Initial Entry
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3. Collection Date:

Date	Location	User	Value	Reason
Oct-19-2020 14:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/17/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-19-2020 14:48:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 329 Identifier: Test:: C Reactive Protein_PX329 Result:: 1.1 Not Done:: Lab Normal Range: Low <0.5 High <0.5 Unit mg/L	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

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Header Text: c4591001

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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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(US & Canada)

5.a Test:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.1	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <0.5 <i>High</i> <0.5 <i>Unit</i> mg/L	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-02-2020 14:54:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: 30 Not Done::	Transcription Error

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject Initials: ---

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			Lab Normal Range: <i>Low</i> <39 <i>High</i> <39 <i>Unit</i> U/L	
Oct-26-2020 15:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: .30 Not Done:: Lab Normal Range: <i>Low</i> <39 <i>High</i> <39 <i>Unit</i> U/L	X10^3/mcl
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: .30 Not Done:: Lab Normal Range: <i>Low</i> <39 <i>High</i> <39	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-03-2020 20:32:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-02-2020 14:54:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Nov-02-2020 14:54:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: 30	Transcription Error
Oct-30-2020 14:47:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clin: Please review the value entered and confirm if the correct value is << 30 >> instead of << 0.30 >>
Oct-26-2020 19:02:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:27:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 00:19:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-21-2020 07:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-20-2020 15:21:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	comment made
Oct-20-2020 06:45:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Previous response noted. Please update the field level comment with the actual 'Unit' of measurement if not available for selection.
Oct-19-2020 14:46:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unit is not listed it is EnzU/L
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: .30	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:25:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <39 <i>High</i> <39 <i>Unit</i> U/L	X10 ³ /mcl
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <39 <i>High</i>	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			<39	
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5.c

Date	Location	User	Value	Reason
Oct-26-2020 15:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28 Result:: 52 Not Done:: Lab Normal Range: <i>Low</i> <42 <i>High</i> <42 <i>Unit</i> U/L	Updated per query
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28 Result:: 52 Not Done:: Lab Normal Range: <i>Low</i> <42 <i>High</i> <42	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject Initials: ---

Generated By: (b) (4)

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:02:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:26:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 00:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update
Oct-21-2020 07:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-20-2020 15:23:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	comment made
Oct-20-2020 06:45:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Previous response noted. Please update the field level comment with the actual 'Unit' of measurement if not available for selection.

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

Oct-19-2020 14:47:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unit is not listed it is EnzU/L
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 52	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:25:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <42 <i>High</i> <42 <i>Unit</i> U/L	Updated per query
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <42 <i>High</i> <42	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-26-2020 15:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined 35 Identifier: Test:: Alkaline Phospha tase_PX35 Result:: 73 Not Done::	Updated per query

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated By: (b) (4)

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			Lab Normal Range: <i>Low</i> 39 <i>High</i> 170.4 <i>Unit</i> U/L	
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Alkaline Phosphatase_PX35 Result:: 73 Not Done:: Lab Normal Range: <i>Low</i> 39 <i>High</i> 170.4	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:03:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:27:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 00:20:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update
Oct-21-2020 07:12:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-20-2020 15:24:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	comment made
Oct-20-2020 06:45:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Previous response noted. Please update the field level comment with the actual 'Unit' of measurement if not available for selection.

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated By: (b) (4)

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5.d Result:				
Date	Location	User	Value	Reason
Oct-19-2020 14:47:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	unit is not listed it is EnzU/L
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 73	Initial Entry

5.d LNMT				
Date	Location	User	Value	Reason
Oct-26-2020 15:26:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 39 <i>High</i> 170.4 <i>Unit</i> U/L	Updated per query
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 39 <i>High</i> 170.4	Initial Entry

5.e				
Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 21 tifier:	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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

			Test::	Bilirubin_P X21	
			Result::	0.4	
			Not Done::		
			Lab Normal Range:	<i>Low</i> <1.0	
				<i>High</i> <1.0	
				<i>Unit</i> mg/dL	

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 15-Sep-2020 21:51**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44**5.e Sponsor ID:**

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.4	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <1.0 <i>High</i> <1.0 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 47 Identifier: Test:: Blood Urea Nitro gen_PX47	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 30	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			8	
			<i>High</i>	
			23	
			<i>Unit</i>	
			mg/dL	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 30	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 8 <i>High</i> 23 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-02-2020 14:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48	Transcription Error

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 1.3 Not Done:: Lab Normal Range <i>Low</i> : 0.7 <i>High</i> 1.2 <i>Unit</i> mg/dL	
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 48 entifier: Test:: Creatinine_P X48 Result:: 1.3 Not Done:: Lab Normal Range <i>Low</i> : 0.7 <i>High</i> 1.2 <i>Unit</i> g/L	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-03-2020 20:33:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-02-2020 14:56:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-30-2020 14:50:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please the Unit should be << mg/dL >> and update as appropriate
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.3	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-02-2020 14:55:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: <i>Low</i> 0.7 <i>High</i> 1.2 <i>Unit</i>	Transcription Error

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Header Text: c4591001

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			mg/dL	
Oct-19-2020 14:45:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.7 <i>High</i> 1.2 <i>Unit</i> g/L	Initial Entry

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Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

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Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

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Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

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Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - Audit Trail

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Form Status:

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Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-12-2020 03:50:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Closed as data updated.
Nov-11-2020 08:09:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 08:09:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital Systems 101 Sivley Avenue Huntsville, Alabam a	Transcription Error
Nov-11-2020 02:03:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM: A carriage return is identified, please do not press enter, tab key or extra space or copy paste, just type lab name all in single line with comma separated. Thank you.
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital Systems 101 Sivley Avnue Huntsville, Alabama	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 329 Test:: C Reactive Protein_PX329 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.b

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28 Result::	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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			Not Done:: NOT DONE Lab Normal Range:	
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5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	Initial Entry

5.c Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 35 Test:: Alkaline Phosphatase_PX35 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 47 Identifier: Test:: Blood Urea Nitro gen_PX47 Result:: 28 Not Done:: Lab Normal Range: Low 8 High 23 Unit mg/dL	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 28	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 8 High 23 Unit mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_P X48	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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			Result:: 1.3	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.7	
			<i>High</i>	
			1.2	
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.3	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:05:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.7 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 329 Identifier: Test:: C Reactive Prote in_PX329 Result:: Not Done:: NOT DONE Lab Normal Ran ge:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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5.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.b

Date	Location	User	Value	Reason
Oct-26-2020 15:28:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Define d Identifier: Test:: Alanine Aminotransferase_PX30 Result:: 38 Not Done:: Lab Normal Range: Low <42 High <42 Unit U/L	Updated per query
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define d Identifier: Test:: Alanine Aminotransferase_PX30 Result:: 38 Not Done::	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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			Lab Normal Range: <i>Low</i> <42 <i>High</i> <42	
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Subject Initials: ---

Generated By: (b) (4)

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-27-2020 07:53:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Unit is present in item comment.
Oct-26-2020 19:04:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:30:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-26-2020 15:28:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Answer Auto Query
Oct-24-2020 03:03:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM1: Response noted, however no comment is added. Please add item level comment if unit is not available in dropdown list.
Oct-24-2020 00:18:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update
Oct-22-2020 08:08:07 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	unit is listed in the comment box due to

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Time (US & Canada)				not being one of the selections in the drop down box.
Oct-22-2020 03:21:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Unit is missing for this test. Please correct or confirm appropriately.
Oct-21-2020 14:13:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 38	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:28:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <42 <i>High</i> <42 <i>Unit</i> U/L	Updated per query
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <42 <i>High</i> <42	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-26-2020 15:29:11 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin 28	Updated per query

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Header Text: c4591001

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(US & Canada)		(b) (4), (b) (6)	ed Identifier: Test:: Aspartate Aminotr ansferase_PX28 Result:: 20 Not Done:: Lab Normal R <i>Low</i> ange: <39 <i>High</i> <39 <i>Unit</i> U/L	
Oct-22-2020 12:38:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defin 28 ed Identifier: Test:: Aspartate Aminotr ansferase_PX28 Result:: 20 Not Done:: Lab Normal R <i>Low</i> ange: <39 <i>High</i> <39	please see comment not available in drop down
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defin 28 ed Identifier: Test:: Aspartate Aminotr ansferase_PX28 Result:: 20 Not Done:: Lab Normal R <i>Low</i> ange: <39 <i>High</i> <3(Initial Entry

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:04:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:31:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 03:03:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical query present for unit
Oct-24-2020 00:18:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update
Oct-22-2020 12:41:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see comment
Oct-22-2020 12:38:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-22-2020 03:22:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Unit is missing for this test. Please correct or confirm appropriately.

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Oct-21-2020 14:13:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 20	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:29:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <39 <i>High</i> <39 <i>Unit</i> U/L	Updated per query
Oct-22-2020 12:38:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <39 <i>High</i> <39	please see comment not available in drop down
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <39 <i>High</i> <39	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-26-2020 15:29:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined 35 Identifier:	Updated per query

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Subject Initials: ---

Generated By: (b) (4)

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

			Test:: Alkaline Phosphate_PX35 Result:: 72 Not Done:: Lab Normal Range: <i>Low</i> 39 <i>High</i> 117 <i>Unit</i> U/L	
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 35 Test:: Alkaline Phosphate_PX35 Result:: 72 Not Done:: Lab Normal Range: <i>Low</i> 39 <i>High</i> 117	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:04:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:32:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 03:03:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical query present for unit
Oct-24-2020 00:19:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update
Oct-22-2020 12:41:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see comment
Oct-22-2020 03:22:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Unit is missing for this test. Please correct or confirm appropriately.
Oct-21-2020 14:14:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

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5.d Result:				
Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72	Initial Entry

5.d LNMT				
Date	Location	User	Value	Reason
Oct-26-2020 15:29:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 39 <i>High</i> 117 <i>Unit</i> U/L	Updated per query
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 39 <i>High</i> 117	Initial Entry

5.e				
Date	Location	User	Value	Reason
Nov-13-2020 08:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Bilirubin_P X21 Result:: 0.3 Not Done::	Transcription Error

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

			Lab Normal Range: <i>Low</i> <1.0 <i>High</i> <1.0 <i>Unit</i> mg/dL	
Nov-11-2020 08:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 21 Test:: Bilirubin_P X21 Result:: 0.3 Not Done:: Lab Normal Range: <i>Low</i> <1.0 <i>High</i> <0.10 <i>Unit</i> mg/dL	Transcription Error
Nov-09-2020 09:06:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: Sponsor-Defined Identifier: 21 Test:: Bilirubin_P X21 Result:: 0.3 Not Done:: Lab Normal Range: <i>Low</i> <1.0 <i>High</i> <.1.0 <i>Unit</i> mg/dL	Transcription Error
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 21 Test:: Bilirubin_P X21	Initial Entry

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			Result:: 0.3	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			<1.0	
			<i>High</i>	
			<.10	
			<i>Unit</i>	
			mg/dL	

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-14-2020 18:57:42 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-13-2020 08:43:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Nov-13-2020 00:02:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clin: Please the Bilirubin normal ranges and Unit should be entered as follow "Low <1.0 High <1.0 mg/dL". Please update accordingly
Nov-11-2020 08:23:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Nov-11-2020 00:54:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	Clin: Please the Bilirubin normal ranges and Unit should be entered as follow "Low <1.0 High <1.0 mg/dL" instead of "Low <1.0 High <.0.10 mg/dL".

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				Please update accordingly
Nov-09-2020 09:06:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	corrected
Nov-07-2020 13:14:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clin: Please the Bilirubin normal ranges and Unit should be entered as follow "Low <1.0 High <1.0 mg/dL" instead of "Low <1.0 High <0.10 mg/dL". Please update accordingly
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.3	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-13-2020 08:43:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <1.0 <i>High</i> <1.0 <i>Unit</i> mg/dL	Transcription Error
Nov-11-2020 08:23:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <1.0 <i>High</i> <0.10 <i>Unit</i> mg/dL	Transcription Error
Nov-09-2020 09:06:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <1.0	Transcription Error

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			<i>High</i> <.1.0 <i>Unit</i> mg/dL	
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED] [REDACTED]	Data Entry: <i>Low</i> <.10 <i>High</i> <.10 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 47 Test:: Blood Urea Nitrogen_PX47 Result:: 24 Not Done:: Lab Normal Range: <i>Low</i> 8 <i>High</i> 23 <i>Unit</i> mg/dL	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 24	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 8 <i>High</i> 23 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_P X48	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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			Result:: 1.0	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.7	
			<i>High</i>	
			1.2	
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:11:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.7 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 14:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-11-2020 13:04:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 08:10:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 08:10:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital Systems 101 S ivley Avenue Huntsville, Alabama	Transcription Error
Nov-11-2020 02:03:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM: A carriage return is identified, please do not press enter, tab key or extra space or copy paste, just type lab name all in single line with comma separated. Thank you.
Oct-21-2020 14:18:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital Systems 101 Sivley Avnue Huntsville, Alabama	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 14:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

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4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 14:20:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 329 Test:: C Reactive Protein_PX329 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.b

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Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-10-2020 08:44:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: 31 Not Done:: Lab Normal Range: <i>Low</i> <42 <i>High</i> <42 <i>Unit</i> U/L	Transcription Error
Oct-26-2020 15:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: 31 Not Done:: Lab Normal Range: <i>Low</i> <42 <i>High</i> ,42 <i>Unit</i> U/L	Updated per query
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 30 Test:: Alanine Aminotransferase_PX30 Result:: 31 Not Done:: Lab Normal Range: <i>Low</i> <42 <i>High</i> ,42	Initial Entry

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-26-2020 20:45:45 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:34:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 03:05:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical query present for unit
Oct-24-2020 00:21:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update
Oct-22-2020 12:44:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see comment
Oct-22-2020 03:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Unit is missing for this test. Please correct or confirm appropriately.
Oct-21-2020 14:19:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-21-2020 14:17:47	ACV0PFEINFP6000	auto query	Query 1: Opened	Result is present, but

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

(UTC-06:00) Central Time (US & Canada)		(autoquery)		lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 31	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-10-2020 11:57:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-10-2020 08:44:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-10-2020 08:44:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <42 <i>High</i> <42 <i>Unit</i> U/L	Transcription Error
Nov-10-2020 05:34:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 1: Opened	Please check high range and remove the invalid character
Oct-26-2020 15:33:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <42 <i>High</i> ,42 <i>Unit</i> U/L	Updated per query
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <42 <i>High</i>	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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Form Version: 10-Oct-2020 15:58

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Subject Initials: ---

Generated By: (b) (4)

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

			,42	
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5.c

Date	Location	User	Value	Reason
Oct-26-2020 15:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28 Result:: 17 Not Done:: Lab Normal Range: <i>Low</i> <39 <i>High</i> <39 <i>Unit</i> U/L	Updated per query
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 28 Test:: Aspartate Aminotransferase_PX28 Result:: 17 Not Done:: Lab Normal Range: <i>Low</i> <39 <i>High</i> <39	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-26-2020 20:46:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:34:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 03:05:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical query present for unit
Oct-24-2020 00:21:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update
Oct-22-2020 12:44:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see comment
Oct-22-2020 03:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Unit is missing for this test. Please correct or confirm appropriately.
Oct-21-2020 14:19:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct
Oct-21-2020 14:17:47	ACV0PFEINFP6000	auto query	Query 1: Opened	Result is present, but

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Header Text: c4591001**Visit:** POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History**Form Version:** 10-Oct-2020 15:58**Form Status:** Data Complete, Frozen, Verified**Site No:** 1047**Site Name:** (1047) Medical Affiliated Research Center**Subject No:** 10471252**Subject Initials:** ---**Generated By:** (b) (4)**Generated Time (GMT):** 29-Mar-2021 04:44

(UTC-06:00) Central Time (US & Canada)		(autoquery)		lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 17	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:33:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <39 <i>High</i> <39 <i>Unit</i> U/L	Updated per query
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <39 <i>High</i> <39	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-26-2020 15:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined 35 Identifier: Test:: Alkaline Phosphatase_PX35 Result:: 67 Not Done::	Updated per query

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Generated By: (b) (4)

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			Lab Normal Range: <i>Low</i> 29 <i>High</i> 117 <i>Unit</i> U/L	
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Alkaline Phosphatase_PX35 Result:: 67 Not Done:: Lab Normal Range: <i>Low</i> 29 <i>High</i> 117	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-26-2020 20:46:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:34:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 03:05:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical query present for unit
Oct-24-2020 00:21:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << U/L >>. Please update
Oct-22-2020 12:45:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please see comment
Oct-22-2020 03:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Unit is missing for this test. Please correct or confirm appropriately.
Oct-21-2020 14:19:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Original value is correct

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Header Text: c4591001

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Site Name: (1047) Medical Affiliated Research Center

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Generated By: (b) (4)

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5.d Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 67	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:33:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 29 <i>High</i> 117 <i>Unit</i> U/L	Updated per query
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 29 <i>High</i> 117	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 21 tifier: Test:: Bilirubin_P X21 Result:: 0.3 Not Done::	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range: <i>Low</i> <1.0 <i>High</i> <1.0 <i>Unit</i> mg/dL	
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5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.3	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <1.0 <i>High</i> <1.0 <i>Unit</i> mg/dL	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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5.f

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 47 Test:: Blood Urea Nitrogen_PX47 Result:: 29 Not Done:: Lab Normal Range: <i>Low</i> 5 <i>High</i> 28 <i>Unit</i> mg/dL	Initial Entry

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Header Text: c4591001

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 29	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 5 <i>High</i> 28 <i>Unit</i> mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_P X48	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.8	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.7	
			<i>High</i>	
			1.2	
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

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Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.8	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:17:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.7 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: CLINICAL CHEMISTRY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-11-2020 13:04:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 08:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 08:05:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Hu ntsville AL 35801	Transcription Error
Nov-11-2020 02:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM: A carriage return is identified, please do not press enter, tab key or extra space or copy paste, just type lab name all in single line with comma separated. Thank you.
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Huntsville AL 35901	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/23/2020	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

4. Specimen Type:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 329 Test:: C Reactive Protein_PX329 Result:: Not Done:: NOT DONE Lab Normal Range:	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 329	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: C Reactive Protein_PX329	Initial Entry

5.a Not Done:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT DONE	Initial Entry

5.b

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Alanine Aminotransferase_PX30 Result:: 33 Not Done:: Lab Normal Range: <i>Low</i> <42 <i>High</i> <42 <i>Unit</i> U/L	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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Subject Initials: ---

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alanine Aminotransferase_PX30	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 33	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <42 <i>High</i> <42 <i>Unit</i> U/L	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Define 28 d Identifier: Test:: Aspartate Aminotransferase_PX28	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 21	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			<39	
			<i>High</i>	
			<39	
			<i>Unit</i>	
			U/L	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 28	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Aspartate Aminotransferase_PX28	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 21	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <39 <i>High</i> <39 <i>Unit</i> U/L	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined 35 Identifier: Test:: Alkaline Phospha tase_PX35	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 65	
			Not Done::	
			Lab Normal Range: <i>Low</i> 39	
			<i>High</i> 117	
			<i>Unit</i> U/L	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 35	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Alkaline Phosphatase_PX35	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 65	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 39 <i>High</i> 117 <i>Unit</i> U/L	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Iden 21 tifier: Test:: Bilirubin_P X21	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: .3	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			<1.0	
			<i>High</i>	
			<1.0	
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 21	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Bilirubin_PX21	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: .3	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> <1.0 <i>High</i> <1.0 <i>Unit</i> mg/dL	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 47 Test:: Blood Urea Nitro gen_PX47	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 25	
			Not Done::	
			Lab Normal Range: <i>Low</i> 22	
			<i>High</i> 29	
			<i>Unit</i> mg/dL	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 47	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Blood Urea Nitrogen_PX47	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 25	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 22 High 29 Unit mg/dL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 48 Test:: Creatinine_P X48	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.9	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.7	
			<i>High</i>	
			1.2	
			<i>Unit</i>	
			mg/dL	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING CHEMISTRY - eCRF Audit Trail History

Form Version: 10-Oct-2020 15:58

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 48	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Creatinine_PX48	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.9	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-09-2020 12:56:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.7 <i>High</i> 1.2 <i>Unit</i> mg/dL	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - Audit Trail

Form Version: 15-Sep-2020 21:55

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Lab Panel:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Dec-02-2020 10:06:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Data updated.
Dec-02-2020 08:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Dec-02-2020 08:12:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Hu ntsville Alabama 35801	Transcription Error
Dec-02-2020 05:08:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	DM RQ1 :A carriage return is still identified, Please click into the enterable page and press delete and backspace multiple times to remove the characters. Do not press enter key, just type lab name all in single line with comma separated.
Nov-11-2020 13:02:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 08:06:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 08:06:05 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Huntsville Hospital Systems 101 S	Transcription Error

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			ivley Huntsville Alabama 35801	
Nov-11-2020 02:05:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM: A carriage return is identified, please do not press enter, tab key or extra space or copy paste, just type lab name all in single line with comma separated. Thank you.
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Huntsville Hospital Systems 101 Sivley Avnue Huntsville, Alabama	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted]	Data Entry: Oct/16/2020	Initial Entry

4. Specimen Type:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 15.4 Not Done::	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range: <i>Low</i> 12.2 <i>High</i> 16.7 <i>Unit</i> g/dL	
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5.a Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 15.4	Initial Entry

5.a LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 12.2 <i>High</i> 16.7 <i>Unit</i> g/dL	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.b

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 2 Test:: Hematocrit_ PX2 Result:: 43.7 Not Done:: Lab Normal Range: <i>Low</i> 38.2 <i>High</i> 49.2 <i>Unit</i> %	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 43.7	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 38.2 <i>High</i> 49.2 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 5.27	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			4.40	
			<i>High</i>	
			5.50	
			<i>Unit</i>	
			10 ⁶ /cu mm	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.c Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 5.27	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.40 <i>High</i> 5.50 <i>Unit</i> 10^6/cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Oct-26-2020 15:37:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5	Updated per query

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 160 Not Done:: Lab Normal Range: <i>Low</i> 137 <i>High</i> 352 <i>Unit</i> 10 ³ /uL	
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Platelets_P X5 Result:: 160 Not Done:: Lab Normal Range: <i>Low</i> 137 <i>High</i> 352	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:01:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:39:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 00:25:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-22-2020 03:32:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 16:15:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	added in comments since it is not an option in the drop down box
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:31:48 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 160	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Generated By: (b) (4)

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

(US & Canada)	(b) (4), (b) (6)
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5.d LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:37:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 137 <i>High</i> 352 <i>Unit</i> 10^3/uL	Updated per query
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 137 <i>High</i> 352	Initial Entry

5.e

Date	Location	User	Value	Reason
Oct-26-2020 15:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_PX7 Result:: 4.63 Not Done:: Lab Normal Range: <i>Low</i> 4.10 <i>High</i> 12.20 <i>Unit</i> 10^3/uL	Updated per query
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_PX7	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 4.63	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			4.10	
			<i>High</i>	
			12.20	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:01:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Oct-26-2020 15:40:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-24-2020 00:25:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-23-2020 03:25:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-22-2020 12:11:29 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please note that this is in the comment because the correct unit is not in the drop down.
Oct-22-2020 03:35:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	DM: Unit is missing for this test. Please correct or confirm appropriately.
Oct-21-2020 16:19:22 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

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Subject No: 10471252

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Generated By: (b) (4)

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Time (US & Canada)				
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [redacted] [redacted]	Data Entry: 4.63	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:37:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	Data Entry: <i>Low</i> 4.10 <i>High</i> 12.20 <i>Unit</i> 10^3/uL	Updated per query
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	Data Entry: <i>Low</i> 4.10 <i>High</i> 12.20	Initial Entry

5.f

Date	Location	User	Value	Reason
Oct-26-2020 15:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) [redacted] (4), [redacted] (b) [redacted] (6) [redacted]	Data Entry: Sponsor-Defined Id 608 entifier: Test:: Neutrophils_P X608 Result:: 2.94 Not Done::	Updated per query

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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			Lab Normal Range <i>Low</i> : 1.50 <i>High</i> 7.90 <i>Unit</i> 10 ³ /uL	
Oct-22-2020 12:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_P X608 Result:: 2.94 Not Done:: Lab Normal Range <i>Low</i> : 1.50 <i>High</i> 7.90	Transcription Error
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 608 Test:: Neutrophils_P X608 Result:: 63.5 Not Done:: Lab Normal Range <i>Unit</i> : %	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:01:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-26-2020 15:40:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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5.f Result:

Date	Location	User	Value	Reason
Oct-24-2020 06:54:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Clin query
Oct-24-2020 00:23:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 3: Opened	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-22-2020 20:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-22-2020 12:17:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	added and units is in comment not available in drop down
Oct-22-2020 12:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Oct-22-2020 12:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-22-2020 12:14:47	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

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Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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

(UTC-06:00) Central Time (US & Canada)			2.94	
Oct-22-2020 05:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW5127417;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-22-2020 03:24:06 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Ranges (low and high) are missing for this test. Please correct or confirm appropriately.
Oct-21-2020 16:18:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 63.5	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:38:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 1.50	UPdated per query

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			High 7.90 Unit 10^3/uL	
Oct-22-2020 12:14:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Low 1.50 High 7.90	Transcription Error
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Unit %	Initial Entry

5.g

Date	Location	User	Value	Reason
Oct-26-2020 15:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_P X609 Result:: 0.0 Not Done:: Lab Normal Range Low : 0.00 High 0.50 Unit 10^3/uL	Updated per query
Oct-22-2020 12:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_P X609 Result:: 0.0 Not Done::	Transcription Error

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Subject Initials: ---

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			Lab Normal Range <i>Low</i> : 0.00 <i>High</i> 0.50	
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 609 Test:: Eosinophils_ PX609 Result:: 0.0 Not Done:: Lab Normal Range :	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:01:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Oct-26-2020 15:40:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Changed data per query
Oct-24-2020 06:54:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Clin query
Oct-24-2020 00:24:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-22-2020	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY	Query 2:	Auto closed by

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20:48:15 (UTC-06:00) Central Time (US & Canada)		(b) (4)	Closed	Validation Check: VC_LB001_08
Oct-22-2020 12:20:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Changed data per query
Oct-22-2020 12:20:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	up dated and units is in comment
Oct-22-2020 12:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-22-2020 05:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 2: Opened	DMW5127412;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-22-2020 03:25:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Result is present, however lab normal ranges (Low, high) and Unit are missing. Please correct or confirm.
Oct-21-2020 16:21:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Original value is correct

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Generated By: (b) (4)

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

Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ry: 0.0	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:38:32 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10 ³ /uL	UPdated per query
Oct-22-2020 12:18:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.50	Transcription Error

5.h

Date	Location	User	Value	Reason
Oct-26-2020 15:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_P X612 Result:: 0.48 Not Done::	Updated per query

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001
Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History
Form Version: 15-Sep-2020 21:55 **Form Status:** Data Complete, Frozen, Verified
Site No: 1047 **Site Name:** (1047) Medical Affiliated Research Center
Subject No: 10471252 **Subject Initials:** ---
Generated By: (b) (4) **Generated Time (GMT):** 29-Mar-2021 04:44

			Lab Normal Range: <i>Low</i> 0.30 <i>High</i> 1.10 <i>Unit</i> 10 ³ /uL	
Oct-22-2020 12:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_P X612 Result:: 0.48 Not Done:: Lab Normal Range: <i>Low</i> : 0.30 <i>High</i> 1.10	not available in dropdown. in comments
Oct-22-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_P X612 Result:: 0.48 Not Done:: Lab Normal Range: <i>Low</i> : 0.30 <i>High</i> 1010	Transcription Error
Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 612 Test:: Monocytes_P X612 Result:: 10.4 Not Done::	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Lab Normal Range:	<i>Unit</i> %
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Result:: Not Done:: Lab Normal Range: :	612 Monocytes_P X612 10.4
				Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:02:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-26-2020 15:40:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Changed data per query
Oct-24-2020 03:04:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	clinical query present for unit
Oct-24-2020 00:24:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-22-2020 20:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_LB001_08

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1047

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Subject Initials: ---

Generated By: (b) (4)

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

Oct-22-2020 12:27:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	not available in drop down in comments
Oct-22-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-22-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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5.h Result:

Date	Location	User	Value	Reason
Oct-22-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.48	Transcription Error
Oct-22-2020 05:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW5127410;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-22-2020 03:27:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	requery present
Oct-22-2020 03:26:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thanks for confirming. Please add an item comment stating the below response.
Oct-21-2020 16:26:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	No normal lab range provided on lab results. % only.
Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1:	no lab normal range

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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

16:22:51 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Answered	provided on lab results. % only
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 10.4	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:38:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.30 <i>High</i> 1.10 <i>Unit</i> 10 ³ /uL	Updated per query
Oct-22-2020 12:23:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.30 <i>High</i> 1.10	not available in drop down. in comments
Oct-22-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.30 <i>High</i> 1010	Transcription Error

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

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Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: <i>Unit</i> %	Initial Entry
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5.i

Date	Location	User	Value	Reason
Oct-26-2020 15:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sponsor-Defined Id 610 entifier: Test:: Basophils_P X610 Result:: 0.0 Not Done:: Lab Normal Range <i>Low</i> : 0.00 <i>High</i> 0.01 <i>Unit</i> 10^3/uL	Updated per query
Oct-22-2020 12:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [Redacted] [Redacted]	Data Entry: Sponsor-Defined Id 610 entifier: Test:: Basophils_P X610 Result:: 0.0 Not Done:: Lab Normal Range <i>Low</i> : 0.00 <i>High</i> 0.01	Transcription Error
Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Id 610 entifier: Test:: Basophils_P X610 Result:: 0.0 Not Done::	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Site Name: (1047) Medical Affiliated Research Center

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			Lab Normal Range <i>Unit</i>	
			: %	
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 610 entifier: Test:: Basophils_P X610 Result:: 0.0 Not Done:: Lab Normal Range :	Initial Entry

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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

5.i Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:02:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-26-2020 15:41:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Changed data per query
Oct-24-2020 06:54:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Clin query
Oct-24-2020 00:24:23 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clin: The Unit should be << 10^3/uL >>. Please update accordingly
Oct-23-2020	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1:	please see comment

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

07:43:20 (UTC-06:00) Central Time (US & Canada)		(b) (4), (b) (6)	Answered	
Oct-23-2020 03:15:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thanks for the response, however unit is still missing, please review and update.
Oct-22-2020 20:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-22-2020 12:31:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	confirm
Oct-22-2020 12:30:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-22-2020 12:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-22-2020 05:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW5127416;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF
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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Oct-22-2020 03:28:47 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	requery present
Oct-22-2020 03:28:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Ranges (low and high) are missing for this test. Please correct or confirm appropriately.
Oct-21-2020 16:26:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	No normal lab range provided on lab results. % only.
Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 16:23:52 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	Changed data per query
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.0	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site Name: (1047) Medical Affiliated Research Center

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Generated By: (b) (4)

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5.i LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:39:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.01 <i>Unit</i> 10 ³ /uL	Updated per query
Oct-22-2020 12:28:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.01	Transcription Error
Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: <i>Unit</i> %	Initial Entry

5.j

Date	Location	User	Value	Reason
Oct-26-2020 15:39:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I 611 dentifier: Test:: Lymphocytes_ PX611 Result:: 1.21 Not Done:: Lab Normal Rang <i>Low</i> e: 1.10 <i>High</i> 3.40 <i>Unit</i> 10 ³ /uL	Updated per query
Oct-22-2020 12:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sponsor-Defined I 611	Transcription Error

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

			dentifier: Test:: Lymphocytes_ PX611 Result:: 1.21 Not Done:: Lab Normal Range: <i>Low</i> 1.10 <i>High</i> 3.40	
Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_ PX611 Result:: 36.3 Not Done:: Lab Normal Range: <i>Unit</i> %	Initial Entry
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 611 Test:: Lymphocytes_ PX611 Result:: 36.3 Not Done:: Lab Normal Range: e:	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Oct-26-2020 19:02:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Closed	Response satisfies query
Oct-26-2020 15:41:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Answered	Changed data per query
Oct-24-2020 06:53:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Closed	Clin query
Oct-24-2020 00:24:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 4: Opened	Clin: The Unit should be << 10^3/uL >>. Please update accordingly

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

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5.j Result:

Date	Location	User	Value	Reason
Oct-23-2020 07:36:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	the unit is not in the drop down but is in the comment section
Oct-23-2020 03:14:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thanks for the response, however unit is not updated yet, please review and update
Oct-22-2020 20:48:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Closed	Auto closed by Validation Check: VC_LB001_08
Oct-22-2020 12:33:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated
Oct-22-2020 12:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 3: Answered	Transcription Error
Oct-22-2020 12:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-22-2020 12:32:19	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

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Header Text: c4591001

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Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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(UTC-06:00) Central Time (US & Canada)			1.21	
Oct-22-2020 05:04:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 3: Opened	DMW5127415;Please confirm that the WBC differentials are entered as absolute values instead of percentages, or correct as appropriate.
Oct-22-2020 03:31:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	requery present
Oct-22-2020 03:30:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued: Opened	DM: Thanks for confirming. Please add an item comment stating the below response.
Oct-21-2020 16:26:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Answered	No normal lab range provided on lab results. % only.
Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Result is present, but lab normal range (Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 16:24:53 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Answered	No normal lab range provided on lab results. % only.
Oct-21-2020 14:31:48	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Result is present, but lab normal range

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

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(UTC-06:00) Central Time (US & Canada)				(Low, high or Unit) is missing. Please correct or confirm.
Oct-21-2020 14:31:48 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.3	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Oct-26-2020 15:39:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.10 <i>High</i> 3.40 <i>Unit</i> 10 ³ /uL	UPdated per query
Oct-22-2020 12:32:19 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.10 <i>High</i> 3.40	Transcription Error
Oct-21-2020 16:25:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: <i>Unit</i> %	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-11-2020 13:03:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 08:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 08:06:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Hu ntsville AL 35801	Transcription Error
Nov-11-2020 02:05:28 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM: A carriage return is identified, please do not press enter, tab key or extra space or copy paste, just type lab name all in single line with comma separated. Thank you.
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Huntsville AL 35801	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020	Initial Entry

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Header Text: c4591001

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4. Specimen Type:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 12.9 Not Done:: Lab Normal Range: <i>Low</i> 12.2 <i>High</i> 16.7 <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
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Generated By: (b) (4)

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Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12.9	Initial Entry
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5.a LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 12.2 <i>High</i> 16.7 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_PX2 Result:: 36.7 Not Done:: Lab Normal Range: <i>Low</i> 38.2 <i>High</i> 49.2 <i>Unit</i> %	Initial Entry

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Generated By: (b) (4)

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 36.7	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 38.2 <i>High</i> 49.2 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 4.34	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			4.40	
			<i>High</i>	
			5.50	
			<i>Unit</i>	
			10 ⁶ /cu mm	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4.34	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.40 <i>High</i> 5.50 <i>Unit</i> 10^6/cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Ident 5 ifier: Test:: Platelets_P X5	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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			Result::	165	
			Not Done::		
			Lab Normal Range:	<i>Low</i>	
				137	
				<i>High</i>	
				352	
				<i>Unit</i>	
				10 ³ /uL	

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Subject Initials: ---

Generated By: (b) (4)

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 165	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 137 <i>High</i> 352 <i>Unit</i> 10^3/uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Leukocytes_PX7	Initial Entry

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Subject Initials: ---

Generated By: (b) (4)

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			Result:: 4.45	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			4.10	
			<i>High</i>	
			12.20	
			<i>Unit</i>	
			10 ⁶ /cu m	
			m	

Header Text: c4591001

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Generated By: (b) (4)

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4.45	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.10 <i>High</i> 12.20 <i>Unit</i> 10^6/cu mm	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 608 entifier: Test:: Neutrophils_P X608	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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			Result:: 2.39	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			1.50	
			<i>High</i>	
			7.90	
			<i>Unit</i>	
			10 ³ /uL	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2.39	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.50 <i>High</i> 7.90 <i>Unit</i> 10 ³ /uL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 609 entifier: Test:: Eosinophils_P X609	Initial Entry

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			Result:: 0.00	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.00	
			<i>High</i>	
			0.50	
			<i>Unit</i>	
			10 ³ /uL	

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5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.00	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10 ³ /uL	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 612 entifier: Test:: Monocytes_P X612	Initial Entry

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Header Text: c4591001

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Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.45	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.30	
			<i>High</i>	
			1.10	
			<i>Unit</i>	
			10 ³ /uL	

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.45	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.30 <i>High</i> 1.10 <i>Unit</i> 10^3/uL	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.01	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.00	
			<i>High</i>	
			0.30	
			<i>Unit</i>	
			10 ³ /uL	

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Header Text: c4591001

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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.01	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.30 <i>Unit</i> 10 ³ /uL	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 611 entifier: Test:: Lymphocytes_ PX611	Initial Entry

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Header Text: c4591001

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Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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			Result:: 1.58	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	1.10
				<i>High</i>
				3.40
				<i>Unit</i>
				10 ³ /uL

Header Text: c4591001

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1.58	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:06:12 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.10 <i>High</i> 3.40 <i>Unit</i> 10 ³ /uL	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-11-2020 13:03:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 07:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 07:53:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Hu ntsville AL 35801	Transcription Error
Nov-11-2020 02:05:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM: A carriage return is identified, please do not press enter, tab key or extra space or copy paste, just type lab name all in single line with comma separated. Thank you.
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Huntsville AK 35801	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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4. Specimen Type:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 13.1 Not Done:: Lab Normal Range: <i>Low</i> 12.2 <i>High</i> 16.7 <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
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Generated By: (b) (4)

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Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13.1	Initial Entry
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5.a LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 12.2 <i>High</i> 16.7 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_ PX2 Result:: 37.0 Not Done:: Lab Normal Range: <i>Low</i> 38.2 <i>High</i> 49.2 <i>Unit</i> %	Initial Entry

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Header Text: c4591001

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.0	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 38.2 <i>High</i> 49.2 <i>Unit</i> %	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3	Initial Entry

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Header Text: c4591001

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Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 4.31	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			4.40	
			<i>High</i>	
			5.50	
			<i>Unit</i>	
			10 ⁶ /cu mm	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4.31	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.40 <i>High</i> 5.50 <i>Unit</i> 10 ⁶ /cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Ident 5 ifier: Test:: Platelets_P X5	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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			Result::	160	
			Not Done::		
			Lab Normal Range:	<i>Low</i>	
				137	
				<i>High</i>	
				352	
				<i>Unit</i>	
				10 ³ /uL	

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Header Text: c4591001

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Generated By: (b) (4)

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5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 160	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 137 <i>High</i> 352 <i>Unit</i> 10^3/uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 7 Test:: Leukocytes_PX7	Initial Entry

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Header Text: c4591001

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Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 4.63	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			4.10	
			<i>High</i>	
			12.20	
			<i>Unit</i>	
			10 ³ /uL	

Header Text: c4591001

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Generated By: (b) (4)

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5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4.63	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.10 <i>High</i> 12.20 <i>Unit</i> 10 ³ /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 608 entifier: Test:: Neutrophils_P X608	Initial Entry

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Generated By: (b) (4)

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			Result:: 12.5	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			1.50	
			<i>High</i>	
			7.90	
			<i>Unit</i>	
			10 ³ /uL	

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5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 12.5	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.50 <i>High</i> 7.90 <i>Unit</i> 10 ³ /uL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 609 entifier: Test:: Eosinophils_P X609	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.00	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.00	
			<i>High</i>	
			0.50	
			<i>Unit</i>	
			10 ³ /uL	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.00	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10 ³ /uL	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 612 entifier: Test:: Monocytes_P X612	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.48	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.30	
			<i>High</i>	
			1.10	
			<i>Unit</i>	
			10 ³ /uL	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.48	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.30 <i>High</i> 1.10 <i>Unit</i> 10 ³ /uL	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.00	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.00	
			<i>High</i>	
			0.30	
			<i>Unit</i>	
			10 ³ /uL	

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.00	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.30 <i>Unit</i> 10 ³ /uL	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 611 entifier: Test:: Lymphocytes_ PX611	Initial Entry

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Header Text: c4591001

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Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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			Result:: 2.94	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	1.50
				<i>High</i>
				7.90
			<i>Unit</i>	
				10 ³ /uL

Header Text: c4591001

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Site No: 1047

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Subject Initials: ---

Generated By: (b) (4)

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5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2.94	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:17:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 1.50 <i>High</i> 7.90 <i>Unit</i> 10 ³ /uL	Initial Entry

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Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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1. Lab Panel:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: HEMATOLOGY	Initial Entry

2. Laboratory Name and Address

Date	Location	User	Value	Reason
Nov-11-2020 13:02:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-11-2020 08:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-11-2020 08:03:27 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Hu ntsville AL 35801	Transcription Error
Nov-11-2020 02:05:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Opened	DM: A carriage return is identified, please do not press enter, tab key or extra space or copy paste, just type lab name all in single line with comma separated. Thank you.
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Huntsville Hospital 101 Sivley Huntsville, AL 35801	Initial Entry

3. Collection Date:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/20/2020	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Form Status: Data Complete, Frozen, Verified

Site No: 1047

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Subject Initials: ---

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4. Specimen Type:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BLOOD	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hemoglobin_PX1 Result:: 13.1 Not Done:: Lab Normal Range: <i>Low</i> 12.2 <i>High</i> 16.7 <i>Unit</i> g/dL	Initial Entry

5.a Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

5.a Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hemoglobin_PX1	Initial Entry

5.a Result:

Date	Location	User	Value	Reason
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

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Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 13.1	Initial Entry
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5.a LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 12.2 <i>High</i> 16.7 <i>Unit</i> g/dL	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Hematocrit_PX2 Result:: 37.1 Not Done:: Lab Normal Range: <i>Low</i> 38.2 <i>High</i> 49.2 <i>Unit</i> 10 ⁶ /cu m m	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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Subject Initials: ---

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5.b Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

5.b Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Hematocrit_PX2	Initial Entry

5.b Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 37.1	Initial Entry

5.b LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 38.2 <i>High</i> 49.2 <i>Unit</i> 10^6/cu mm	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: Test:: Erythrocytes_PX3	Initial Entry

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Header Text: c4591001

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Form Status: Data Complete, Frozen, Verified

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Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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			Result:: 4.36	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			4.40	
			<i>High</i>	
			5.50	
			<i>Unit</i>	
			10 ⁶ /cu mm	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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5.c Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 3	Initial Entry

5.c Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Erythrocytes_PX3	Initial Entry

5.c Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 4.36	Initial Entry

5.c LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.40 <i>High</i> 5.50 <i>Unit</i> 10 ⁶ /cu mm	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Ident 5 ifier: Test:: Platelets_P X5	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

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Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result::	172	
			Not Done::		
			Lab Normal Range:	<i>Low</i>	
				137	
				<i>High</i>	
				352	
				<i>Unit</i>	
				10 ³ /uL	

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

5.d Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 5	Initial Entry

5.d Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Platelets_PX5	Initial Entry

5.d Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 172	Initial Entry

5.d LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 137 <i>High</i> 352 <i>Unit</i> 10^3/uL	Initial Entry

5.e

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 7 Test:: Leukocytes_PX7	Initial Entry

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Header Text: c4591001

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Generated By: (b) (4)

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			Result:: 5.80	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			4.10	
			<i>High</i>	
			12.20	
			<i>Unit</i>	
			10 ³ /uL	

Header Text: c4591001

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Subject Initials: ---

Generated By: (b) (4)

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

5.e Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 7	Initial Entry

5.e Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Leukocytes_PX7	Initial Entry

5.e Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 5.80	Initial Entry

5.e LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 4.10 <i>High</i> 12.20 <i>Unit</i> 10 ³ /uL	Initial Entry

5.f

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 608 entifier: Test:: Neutrophils_P X608	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 3.35	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			1.50	
			<i>High</i>	
			7.90	
			<i>Unit</i>	
			10 ³ /uL	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.f Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 608	Initial Entry

5.f Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Neutrophils_PX608	Initial Entry

5.f Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 3.35	Initial Entry

5.f LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 1.50 <i>High</i> 7.90 <i>Unit</i> 10 ³ /uL	Initial Entry

5.g

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 609 entifier: Test:: Eosinophils_P X609	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.00	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.00	
			<i>High</i>	
			0.50	
			<i>Unit</i>	
			10 ³ /uL	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.g Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 609	Initial Entry

5.g Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Eosinophils_PX609	Initial Entry

5.g Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.00	Initial Entry

5.g LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10 ³ /uL	Initial Entry

5.h

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 612 entifier: Test:: Monocytes_P X612	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.44	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.30	
			<i>High</i>	
			1.10	
			<i>Unit</i>	
			10 ³ /uL	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.h Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 612	Initial Entry

5.h Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Monocytes_PX612	Initial Entry

5.h Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.44	Initial Entry

5.h LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.30 <i>High</i> 1.10 <i>Unit</i> 10^3/uL	Initial Entry

5.i

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Identifier: 610 Test:: Basophils_P X610	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 **Form:** LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 0.02	
			Not Done::	
			Lab Normal Range: <i>Low</i>	
			0.00	
			<i>High</i>	
			0.50	
			<i>Unit</i>	
			10 ³ /uL	

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.i Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 610	Initial Entry

5.i Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Basophils_PX610	Initial Entry

5.i Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 0.02	Initial Entry

5.i LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: <i>Low</i> 0.00 <i>High</i> 0.50 <i>Unit</i> 10 ³ /uL	Initial Entry

5.j

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sponsor-Defined Id 611 entifier: Test:: Lymphocytes_ PX611	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020

Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			Result:: 1.86	
			Not Done::	
			Lab Normal Range <i>Low</i>	
			:	1.10
				<i>High</i>
				3.40
				<i>Unit</i>
				10 ³ /uL

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Oct/14/2020 Form: LOCAL LABORATORY DATA - REPEATING Hematology - eCRF Audit Trail History

Form Version: 10-Oct-2020 16:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.j Sponsor ID:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	<u>Data Entry:</u> 611	Initial Entry

5.j Test:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> Lymphocytes_PX611	Initial Entry

5.j Result:

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 1.86	Initial Entry

5.j LNMT

Date	Location	User	Value	Reason
Nov-09-2020 13:29:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> <i>Low</i> 1.10 <i>High</i> 3.40 <i>Unit</i> 10 ³ /uL	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - COVID - Audit Trail
Oct/14/2020

Form Version: 15-Sep-2020 21:52

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-19-2020 14:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Oct/14/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date:

Date	Location	User	Value	Reason
Oct-19-2020 14:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/18/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-21-2020 09:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 130 Diastolic:: 72 Respiratory Rate in respirations/minute: Not Done Heart Rate in beats/minute: 47	Initial Entry
Oct-19-2020 14:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Systolic:: 130 Diastolic:: 72 Respiratory Rate in respirations/minute: Heart Rate in beats/minute: 47	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 14:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a Systolic:

Date	Location	User	Value	Reason
Oct-19-2020 14:51:49 (UTC-06:00) Central Time	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 130	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - COVID - eCRF Audit Trail History
Oct/14/2020

Form Version: 15-Sep-2020 21:52

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

(US & Canada)		(b) (4), (b) (6)	
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2.a Diastolic:

Date	Location	User	Value	Reason
Oct-19-2020 14:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 72	Initial Entry

2.a Respiratory Rate in respirations/minute:

Date	Location	User	Value	Reason
Oct-22-2020 03:19:50 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-21-2020 09:11:55 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	updated to not done comment
Oct-21-2020 09:09:44 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Not Done	Initial Entry
Oct-21-2020 03:04:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: The response for "Respiratory Rate in respirations/minute" is missing. Kindly review and update.

2.a Heart Rate in beats/minute:

Date	Location	User	Value	Reason
Oct-19-2020 14:51:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 47	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Oct/14/2020

Form Version: 15-Sep-2020 21:54

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-19-2020 14:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Oct/14/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date:

Date	Location	User	Value	Reason
Oct-19-2020 14:54:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Oct-19-2020 14:54:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Transcription Error
Oct-19-2020 14:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Date is before Date of First Symptom Started on the Signs and Symptoms form in the same visit. Please review and update as appropriate.
Oct-19-2020 14:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/8/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-19-2020 14:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 80.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 14:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Oct/14/2020

Form Version: 15-Sep-2020 21:54

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Oct-19-2020 14:54:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 80.0	Initial Entry
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Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** VITAL SIGNS - PULSE OX ROOM AIR - Audit Trail
Oct/14/2020

Form Version: 10-Oct-2020 16:04

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-19-2020 14:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: VITAL SIGNS - PULSE OX ROOM AIR - eCRF Audit Trail History
Oct/14/2020

Form Version: 10-Oct-2020 16:04

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date:

Date	Location	User	Value	Reason
Oct-19-2020 14:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/19/2020	Initial Entry

2.a

Date	Location	User	Value	Reason
Oct-19-2020 14:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Record Identifier:: 1 Oxygen Saturation: 95.0	Initial Entry

2.a Record Identifier:

Date	Location	User	Value	Reason
Oct-19-2020 14:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 1	Initial Entry

2.a SPO2 Pulse Oximetry %

Date	Location	User	Value	Reason
Oct-19-2020 14:54:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 95.0	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - Audit Trail
Oct/14/2020

Form Version: 06-Jul-2020 21:53

Form Status:

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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Date	Location	User	Value	Reason
Oct-20-2020 16:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: IMAGING - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Assessment:

Date	Location	User	Value	Reason
Oct-20-2020 16:36:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/16/2020	Initial Entry

2. Location of Assessment:

Date	Location	User	Value	Reason
Oct-20-2020 16:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CHEST	Initial Entry

3. Type of Imaging Exam:

Date	Location	User	Value	Reason
Oct-20-2020 16:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: CT SCAN	Initial Entry

4. Assessment:

Date	Location	User	Value	Reason
Nov-12-2020 13:00:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-12-2020 08:50:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-12-2020 08:50:20 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> Lungs: Multifocal ground glass opacities scattered throughout the lungs bilaterally. No Pleura effusions. Extensive coronary atherosclerotic classifications. Normal thickness of the Pericardium	Transcription Error

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on Form: IMAGING - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

			m.	
Nov-11-2020 23:52:24 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	DM1: Thank you for your response. A carriage return is still present, please retype this field without extra space or without pressing enter or tab key or copy paste. Thank you
Nov-11-2020 08:09:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	Transcription Error
Nov-11-2020 08:09:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> Lungs:multifocal groundglass o pacities scattered throughout th e lungs bilaterally No pleura effusions. extensive coronary at herosclerotic classifications No rml thickness of the pericardiu m	Transcription Error
Nov-11-2020 01:46:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Opened	DM: A carriage return is identified, please retype this field without extra space or without pressing enter, tab key or copy paste to avoid error. Thank you.
Oct-28-2020 02:01:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Oct-27-2020 10:27:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Oct-27-2020 10:27:39 (UTC-06:00) Central	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: ABNORMAL	Transcription Error

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: POT_COVID_ILL 1 - Unscheduled Visit on **Form:** IMAGING - eCRF Audit Trail History
Oct/14/2020

Form Version: 06-Jul-2020 21:53

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Time (US & Canada)			<i>If abnormal, specify findings:</i> Lungs:multifocal groundglass opacities scattered throughout the lungs bilaterally No pleura effusions extensive coronary atherosclerotic classifications Normal thickness of the pericardium	
Oct-27-2020 08:31:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	DM: A carriage is identified. To avoid processing errors, please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Oct-20-2020 16:35:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ABNORMAL <i>If abnormal, specify findings:</i> Lungs: multifocal groundglass opacities scattered throughout the lungs bilaterally No pleura effusions extensive coronary atherosclerotic classifications Normal thickness of the pericardium	Initial Entry

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Header Text: c4591001**Visit:** POT_COVID_CONVA 1 - Unscheduled Visit on Nov/13/2020**Form Version:** 22-Apr-2020 21:04**Site No:** 1047**Subject No:** 10471252**Generated By:** (b) (4)**Form:** DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail History**Form Status:** Data Complete, Frozen, Verified**Site Name:** (1047) Medical Affiliated Research Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**I. Date of Visit**

Date	Location	User	Value	Reason
Nov-20-2020 02:15:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Clo sed	Response satisfies query
Nov-19-2020 08:22:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Ans wered	added sorry added it yesterday but must have not submitted correctly
Nov-19-2020 05:47:09 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 2: Op ened	SAE RECON:AER#2020455722 acute coronary syndrome(onset 25Sep2020)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-15-2020 12:10:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Clo sed	Response satisfies query
Nov-15-2020 10:58:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Query 1: Ans wered	patient had V2 and Covid Conv combined
Nov-14-2020 01:21:28 (UTC-06:00)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	DMW QUERY (b) (4)	Query 1: Op ened	DMW5380127;The Date of Visit at COVID_A1 is same as the Date of Visit at

Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/13/2020

Form: DATE OF VISIT - ILLNESS CONVALESCENT - eCRF Audit Trail
History

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Form Status: Data Complete, Frozen, Verified

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Site Name: (1047) Medical Affiliated Research Center

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Subject Initials: ---

Generated By: (b) (4)

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Central Time (US & Canada)				V2_VAX2_L. Please review for duplication and update as appropriate.
Nov-13-2020 13:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry : Nov/1 3/202 0	Initial Entry

3. COVID-19 Illness Visit:

Date	Location	User	Value	Reason
Nov-13-2020 13:59:15 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COVID_A1	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/13/2020

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Nov-13-2020 14:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Nov-13-2020 14:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Nov-13-2020 14:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-13-2020 14:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Nov-13-2020 14:13:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Nov/13/2020	Initial Entry

5.a

Date	Location	User	Value	Reason
Nov-13-2020 14:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSXXR	Initial Entry

5.a Sample ID

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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/13/2020

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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Date	Location	User	Value	Reason
Nov-13-2020 14:14:10 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSXXR	Initial Entry

5.b

Date	Location	User	Value	Reason
Nov-13-2020 14:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSXXS	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 14:14:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSXXS	Initial Entry

5.c

Date	Location	User	Value	Reason
Nov-13-2020 14:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSXXT	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 14:14:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSXXT	Initial Entry

5.d

Date	Location	User	Value	Reason
Nov-13-2020 14:14:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BSHP4R	Initial Entry

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Header Text: c4591001

Visit: POT_COVID_CONVA 1 - Unscheduled
Visit on Nov/13/2020

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ELECTRONIC SAMPLE TRACKING - IMMUNOGENICITY -
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Form Status: Data Complete, Frozen, Verified

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Subject Initials: ---

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5.d Sample ID

Date	Location	User	Value	Reason
Nov-13-2020 14:14:46 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BSHP4R	Initial Entry

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - Audit Trail

Form Status:

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Form Created	

Header Text: c4591001

Visit: Logs - Unscheduled

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Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1047) Medical Affiliated Research Center

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1. Category:

Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 1	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Dec-01-2020 16:28:13 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Closed	Response satisfies query
Nov-30-2020 23:10:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-30-2020 12:54:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	Subject was on Propafenone, It had initially been omitted from our con med sheet, further review of records and a listing was found from patient. It has been added to our con-med list
Nov-30-2020 09:21:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	Original value is correct
Nov-24-2020 22:35:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	Clinical - Thank you. If subject was never on Propafenone, please delete reference to this medication in SAE

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Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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Subject Initials: ---

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				narrative.
Nov-24-2020 09:49:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Reissued:Opened	Clinical Please clarify in SAE update if this event is diagnosable as non-ST elevation acute myocardial infarction or not, with troponin peak of 117; please use the more specific term if appropriate.
Nov-23-2020 08:01:17 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	SAE follow up coming after PI signs. We did not have a record of Propafenone on the subjects chart he had not given us this information
Nov-23-2020 07:57:36 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Answered	I have a follow up SAE submission coming after the PI signs today. There was not mention of ST elevation in the report.
Nov-22-2020 20:54:30 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 3: Opened	CLINICAL In a SAE safety update, please clarify if ST elevation occurred or not; ECG reading not provided.
Nov-21-2020 14:34:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Reissued:Opened	CLINICAL Thank you; SAE update states 'Propafenone discontinued and Metoprolol discontinued'; however, there is no report that subject was ever receiving propafenone. Please review and update concerning

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				propafenone initiation.
Nov-21-2020 14:32:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-20-2020 12:24:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	in process will submit on monday
Nov-20-2020 12:22:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	added
Nov-19-2020 12:58:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Opened	Clinical Please submit a safety followup with additional clinical information including ECG data (ST elevation), treatment for 100% thrombotic occlusion RCA, and any relationship to later COVID diagnosis
Nov-19-2020 12:55:40 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	Clinical On review of the SAE report for Acute Coronary Syndrome, an event of LBBB has been mentioned, yet it does not appear in the CRF. Please review for safety and update AE log CRF accordingly.
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: acute coronary syndrome	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020 10:43	Initial Entry

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Header Text: c4591001

Visit: Logs - Unscheduled

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Subject Initials: ---

Generated By: (b) (4)

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		(b) (4), (b) (6)	
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5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/27/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
Nov-19-2020 08:21:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 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 medical event (i.e. may jeopardize subject and may require medical/surgical intervention to prevent above outcomes).

Date	Location	User	Value	Reason
Nov-20-2020 02:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	For AE acute coronary syndrome: Response to "Is the adverse event serious?" is 'Yes' but "Serious Adverse Event Number" is blank.
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Is this serious event associated with congenital anomaly or birth defect? NO	Initial Entry

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			<p>Did this serious event result in death?</p> <p>NO</p> <p>Did this serious event require or prolong hospitalization?</p> <p>YES</p> <p>Did this serious event result in persistent or significant disability/incapacity?</p> <p>NO</p> <p>Is this serious event life threatening?</p> <p>NO</p> <p>Other medically important serious event</p> <p>NO</p>	
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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
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Feb-16-2021 18:22:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Feb-02-2021 14:22:33 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Answered	We are saying that the history Type 2 diabetes and history of A FIB contributed to the clot that had to

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Subject No: 10471252

Generated By: (b) (4)

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Form Status: Data Complete, Frozen

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Subject Initials: ---

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				be stented.
Feb-02-2021 07:41:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Opened	Clinical 'other reason' for event is T3DM & A fib; however, SAE report describes 100% thrombus in Rt. coronary artery, treated by stent. Please review, harmonize reporting & update where appropriate
Feb-01-2021 19:22:11 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 2: Candidate	Clinical 'other reason' for event is T3DM & A fib; however, SAE report describes 100% thrombus in Rt. coronary artery, treated by stent. Please review, harmonize reporting & update where appropriate
Nov-23-2020 23:29:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Closed	Response satisfies query
Nov-23-2020 07:58:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-23-2020 07:58:38 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> history of diabetes type 2 and atrial fibrillation	Transcription Error
Nov-23-2020 07:16:14 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) [REDACTED]	Query 1: Opened	DM: A carriage is identified. To avoid processing errors,

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

				please remove the identified character by deleting the entry and re-entering the data (without using copy and paste).
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT RELATED If Not Related to study treatment (s), this event is due to: OTHER <i>If Other, specify:</i> history of DMII and history of Atrial Fibrillation	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry

11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry
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14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-19-2020 08:21:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

15. Serious Adverse Event Number: For Pfizer Use Only

Date	Location	User	Value	Reason
Nov-20-2020 02:15:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: 2020455722	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Logs - Unscheduled

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: ADVERSE EVENT REPORT - eCRF Audit Trail History

Form Status: Data Complete, Frozen

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Category:

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ADVERSE EVENT	Initial Entry

2. AE ID:

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 2	Initial Entry

3. Adverse Event:

(If possible specify diagnosis, not individual symptoms)

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: left bundle branch block	Initial Entry

4. Start Date Time:

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sep/25/2020 10:43	Initial Entry

5. Is the adverse event still ongoing?

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO End Date Time: Sep/27/2020 UNK:UNK	Initial Entry

6. Toxicity Grade:

Date	Location	User	Value	Reason
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> 2	Initial Entry
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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).

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

8. Is this adverse event the result of a study Medication Error?

If Yes, record the type of medication error on the Medication Error Log.

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NO	Initial Entry

9. Is this event related to study treatment:

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> NOT RELATED If Not Related to study treatment(s) , this event is due to: OTHER If Other, specify: history of diabetes type 2 and a trial fibrillation	Initial Entry

10. Latest Action Taken with Study Treatment:

Date	Location	User	Value	Reason
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090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NOT APPLICABLE	Initial Entry
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11. Was a Concomitant Medication given?

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

12. Was a Non-Drug Treatment given?

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

13. What was the outcome of this adverse event?:

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: RECOVERED/RESOLVED	Initial Entry

14. Did the adverse event cause the subject to be discontinued from the study?

Date	Location	User	Value	Reason
Nov-20-2020 12:22:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001**Visit:** End of Treatment - Unscheduled**Form Version:** 15-Sep-2020 21:55**Site No:** 1047**Subject No:** 10471252**Generated By:** (b) (4)**Form:** DISPOSITION - TREATMENT - eCRF Audit Trail History**Form Status:** Data Complete, Locked, Frozen, Verified**Site Name:** (1047) Medical Affiliated Research Center**Subject Initials:** ---**Generated Time (GMT):** 29-Mar-2021 04:44[Back to Form](#)**1. Date of Completion/Discontinuation/Death :**

Date	Location	User	Value	Reason
Nov-06-2020 13:29:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-06-2020 07:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	updated per query
Nov-06-2020 07:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Oct/12/2020	updated per query
Nov-06-2020 01:37:31 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Opened	CLINQUERY: Please update date to match the Date of First Symptom Started (e.g. 12Oct2020) on the COV ILL COVID_A CRF.
Nov-05-2020 15:44:05 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Candidate	CLINQUERY: Please update date to match the Date of First Symptom Started (e.g. 12Oct2020) on the COV ILL COVID_A CRF.
Oct-22-2020 08:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: Oct/14/2020	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Oct-22-2020 08:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: VACCINATION	Initial Entry

3. Status:

Date	Location	User	Value	Reason
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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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Nov-10-2020 11:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Closed	Close Auto Query
Nov-10-2020 11:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Opened	Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing.
Nov-09-2020 09:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Closed	Close Auto Query
Nov-09-2020 09:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Opened	Response to "Status" is NO LONGER MEETS ELIGIBILITY CRITERIA but "Specify Status" is missing.
Oct-22-2020 08:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: NO LONGER MEETS ELIGIBILITY CRITERIA	Initial Entry

4. Specify Status:

Date	Location	User	Value	Reason
Nov-16-2020 06:08:54 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Closed	Response satisfies query
Nov-15-2020 15:02:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 2: Answered	query answered
Nov-15-2020 15:02:56 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: The subject was diagnosed and had symptomatic COVID	query answered

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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: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Nov-14-2020 22:48:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	Balaji Prabu R (b) (4)	Query 2: Opened	Please confirm reason patient discontinued treatment? If due to a positive covid test, please enter 'subject tested positive for COVID 19' in specify status field
Nov-14-2020 09:30:03 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 2: Candidate	Please confirm reason patient discontinued treatment? If due to a positive covid test, please enter 'subject tested positive for COVID 19' in specify status field
Nov-11-2020 06:37:39 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Closed	Response satisfies query
Nov-10-2020 11:11:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: completed	Initial Entry
Nov-10-2020 11:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Answered	Transcription Error
Nov-10-2020 11:03:37 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	Transcription Error

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: End of Treatment - Unscheduled

Form: DISPOSITION - TREATMENT - eCRF Audit Trail History

Form Version: 15-Sep-2020 21:55

Form Status: Data Complete, Locked, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Nov-10-2020 09:00:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Reissued:Opened	page is unfrozen please update thank you
Nov-09-2020 09:28:35 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: will continue in the study	Initial Entry
Nov-09-2020 09:28:04 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry:	removed per query
Nov-09-2020 09:05:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Query 1: Answered	please unfreeze page so I can answer the query
Nov-09-2020 02:46:00 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000.InFormAdapter.Discrepancy	PFE SDQ PROD (b) (4)	Query 1: Opened	Please review Specify Status field, the following text was indicated in the comment field [positive covid test]. Any symptoms, AEs or other key data should be collected on the appropriate page. Please review and update as necessary. "[suryas18 SDQ=41548]"
Oct-22-2020 08:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6) (b) (4), (b) (6)	Data Entry: positive COVID test	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form: DATE OF VISIT - eCRF Audit Trail History

Form Version: 22-Apr-2020 21:02

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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I. Date of Visit

Date	Location	User	Value	Reason
Feb-04-2021 10:25:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Potential ReVax Initial Contact -
Unscheduled

Form Version: 10-Dec-2020 02:25

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: FURTHER VACCINATION CONFIRMATION - eCRF Audit Trail
History

Form Status: Data Complete, Frozen

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Select appropriate response - Is participant willing to return for Vaccination 3?

Date	Location	User	Value	Reason
Feb-04-2021 10:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-04-2021 10:25:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	The response indicates participant was unblinded, however the TREATMENT UNBLINDED date is missing in the DISP visit. Please complete this date.
Feb-04-2021 10:25:07 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Participant is willing to return for Vaccination 3 Participant is: eligible per local/national reco mmendations and confirmed to have received only placebo at V accination 1/2	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Disposition - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: TREATMENT UNBLINDED - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Date Treatment Unblinded :

Date	Location	User	Value	Reason
Feb-04-2021 10:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/3/2021	Initial Entry

2. Primary Reason for Unblinding:

Date	Location	User	Value	Reason
Feb-04-2021 10:25:16 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: ASSESS ELIGIBILITY FOR ADD ITIONAL VACCINATION	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Feb-11-2021 14:18:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: INFORMED CONSENT - FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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I. Consent Was:

Date	Location	User	Value	Reason
Feb-11-2021 14:19:59 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: OBTAINED Date Written Consent Obtained Feb/10/2021	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form: DISPOSITION - SCREENING FOR FURTHER VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:31

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Date of Completion/Discontinuation/Death :

Date	Location	User	Value	Reason
Feb-11-2021 14:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021	Initial Entry

2. Phase of Disposition:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: REPEAT SCREENING 1	Initial Entry

3. Status:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:22 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: COMPLETED	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-11-2021 15:29:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-11-2021 15:29:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SERUM	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-11-2021 15:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 15:29:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 15:29:57 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 15:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSYMN	Initial Entry

5.a Sample ID

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-11-2021 15:30:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSYMN	Initial Entry

5.b

Date	Location	User	Value	Reason
Feb-11-2021 15:30:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSYMP	Initial Entry

5.b Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 15:30:18 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSYMP	Initial Entry

5.c

Date	Location	User	Value	Reason
Feb-11-2021 15:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BPSYMR	Initial Entry

5.c Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 15:30:26 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BPSYMR	Initial Entry

5.d

Date	Location	User	Value	Reason
Feb-11-2021 15:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BLB6SH	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

5.d Sample ID

Date	Location	User	Value	Reason
Feb-11-2021 15:30:41 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BLB6SH	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Feb-11-2021 15:30:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Feb-11-2021 15:30:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Feb-11-2021 15:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Feb-11-2021 15:30:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Feb-11-2021 15:30:51 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Feb/10/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Feb-11-2021 15:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ2J6	Initial Entry

5.a Sample ID

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V101_VAX3

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Feb-11-2021 15:31:01 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: BRJ2J6	Initial Entry

Header Text: c4591001

Visit: V101_VAX3

Form Version: 10-Dec-2020 02:26

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Feb/10/2021 15:29	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V101_VAX3

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

7. Route:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Feb-11-2021 14:20:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form Version: 22-Apr-2020 21:02

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: DATE OF VISIT - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Date of Visit

Date	Location	User	Value	Reason
Mar-01-2021 14:03:58 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2021	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

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1. Data Origin

Date	Location	User	Value	Reason
Mar-01-2021 14:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SITE	Initial Entry

2. Sample Type

Date	Location	User	Value	Reason
Mar-01-2021 14:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: NASAL_SWAB	Initial Entry

3. Sample Collected?

Date	Location	User	Value	Reason
Mar-01-2021 14:04:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Deleted	Close Auto Query
Mar-01-2021 14:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto query (autoquery)	Query 1: Candidate	'Sample Collected?' is Yes, however no barcodes are entered. Please review and correct as appropriate.
Mar-01-2021 14:04:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES Date of Collection: Mar/1/2021	Initial Entry

5.a

Date	Location	User	Value	Reason
Mar-01-2021 14:04:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Sample ID: BRJ2MV	Initial Entry

5.a Sample ID

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V102_VAX4

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

Form Version: 22-Apr-2020 21:03

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

Date	Location	User	Value	Reason
Mar-01-2021 14:04:21 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	<u>Data Entry:</u> BRJ2MV	Initial Entry

Header Text: c4591001

Visit: V102_VAX4

Form Version: 10-Dec-2020 02:26

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: VACCINATION - eCRF Audit Trail History

Form Status: Data Complete, Frozen, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Was there a temporary delay of vaccination?

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: NO	Initial Entry

2. Treatment Name

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: BNT162b2	Initial Entry

3. Formulation:

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INJECTION	Initial Entry

4. Dose Date Time:

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Mar/1/2021 14:03	Initial Entry

5. Anatomical Location:

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DELTOID MUSCLE	Initial Entry

6. Body Side:

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: LEFT	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: V102_VAX4

Form: VACCINATION - eCRF Audit Trail History

Form Version: 10-Dec-2020 02:26

Form Status: Data Complete, Frozen, Verified

Site No: 1047

Site Name: (1047) Medical Affiliated Research Center

Subject No: 10471252

Subject Initials: ---

Generated By: (b) (4)

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

7. Route:

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: INTRAMUSCULAR	Initial Entry

8. Actual Dose:

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30.0	Initial Entry

9. Unit:

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ug	Initial Entry

10. Timeframe Subject Was Observed

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: 30 MINUTES	Initial Entry

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

Date	Location	User	Value	Reason
Mar-01-2021 14:16:02 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: YES	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Subject Status - Unscheduled

Form Version: 22-Apr-2020 21:03

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: SUBJECT STATUS - eCRF Audit Trail History

Form Status: Data Complete, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Subject Status

Date	Location	User	Value	Reason
Oct-22-2020 08:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: DISCONTINUED	Initial Entry
Sep-21-2020 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: ENROLLED/RANDOMIZED	Initial Entry
Sep-21-2020 13:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: SCREENED	Initial Entry

2. Subject Status Date

Date	Location	User	Value	Reason
Nov-06-2020 07:56:49 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/12/2020	updated per query
Oct-22-2020 08:11:43 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Oct/14/2020	Initial Entry
Sep-21-2020 13:54:34 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry
Sep-21-2020 13:54:08 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	auto calc (autocalc)	Data Entry: Sep/21/2020	Initial Entry

090177e196ae3084\Final\Final On: 01-Apr-2021 04:08 (GMT)

Header Text: c4591001

Visit: Investigator Signature - Unscheduled

Form Version: 22-Apr-2020 21:04

Site No: 1047

Subject No: 10471252

Generated By: (b) (4)

Form: CASEBOOK SIGNATURE FORM - eCRF Audit Trail History

Form Status: Data Complete, Signed, Verified

Site Name: (1047) Medical Affiliated Research Center

Subject Initials: ---

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

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1. Casebook Signature

Date	Location	User	Value	Reason
Nov-16-2020 15:31:25 (UTC-06:00) Central Time (US & Canada)	ACV0PFEINFP6000	(b) (4), (b) (6)	Data Entry: Click Here to Enable	Initial Entry